

1 **UNITED STATES DISTRICT COURT**
2 **FOR THE DISTRICT OF NEW JERSEY**

3 **IN RE: VALSARTAN, LOSARTAN, CIVIL ACTION NUMBER:**
4 **and IRBESARTAN PRODUCTS 1:19-md-02875-RMB-SAK**
5 **LIABILITY LITIGATION. Pretrial Conference/Motions**
6 **Hearing**

7 Mitchell H. Cohen Building & U.S. Courthouse
8 4th and Cooper Streets
9 Camden, New Jersey 08101
 Tuesday, July 23, 2024
 Commencing at 9:59 a.m.

10 **B E F O R E:** **THE HONORABLE RENÉE MARIE BUMB, CHIEF**
11 **UNITED STATES DISTRICT JUDGE, and**
 THOMAS I. VANASKIE (RET.), SPECIAL MASTER

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(Appearances continued onto next page)

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Larry MacStravic, The Courtroom Deputy

Loretta Smith, Esquire, Judicial Law Clerk to the Honorable
Robert B. Kugler (Ret.)

Terry Henry, Esquire, Hetero

1 (PROCEEDINGS held in open court before the Honorable
2 Renée Marie Bumb, Chief U.S. District Judge, and Thomas I.
3 Vanaskie (Ret.), Special Master, at 9:59 a.m. as follows:)

4 THE COURTROOM DEPUTY: All rise.

5 CHIEF JUDGE BUMB: Good morning.

6 MR. SLATER: Good morning, Your Honor.

7 MS. ALLON: Good morning, Your Honor.

8 MR. HONIK: Good morning.

9 CHIEF JUDGE BUMB: Nice to see you all. Have a seat,
10 please.

11 Okay. I'll get started by getting to know all of
12 you. I'm going to do a little seating chart.

13 All right. So this is the valsartan matter, MDL
14 No. 19-2875. So let me start, I'm going to take appearances
15 from plaintiff, so let me start there.

16 MR. SLATER: Good morning, Your Honor. Adam Slater
17 on behalf of the plaintiffs.

18 CHIEF JUDGE BUMB: Good morning.

19 MR. NIGH: Good morning, Your Honor. Daniel Nigh on
20 behalf of the plaintiffs.

21 CHIEF JUDGE BUMB: Good morning.

22 MR. HONIK: Good morning, Your Honor. Ruben Honik
23 for plaintiffs.

24 CHIEF JUDGE BUMB: Good morning.

25 MS. WHITELEY: Good morning, Your Honor. Conlee

1 Whiteley on behalf of plaintiffs.

2 CHIEF JUDGE BUMB: Good morning.

3 Defendants. And you'll tell me which defendants.

4 MS. ALLON: Good morning, Your Honor. Devora Allon
5 from Kirkland & Ellis for Torrent.

6 CHIEF JUDGE BUMB: Good morning.

7 MS. BRANCATO: Good morning, Your Honor. Alexia
8 Brancato also from Kirkland, also for Torrent.

9 CHIEF JUDGE BUMB: Good morning.

10 MS. BRANCATO: Good morning.

11 MS. ROSE: Good morning, Your Honor. Nina Rose, from
12 Skadden Arps for the ZHP Defendants.

13 CHIEF JUDGE BUMB: Good morning.

14 MS. LOCKARD: Good morning, Your Honor. It's
15 Victoria Lockard from Greenberg Traurig. I represent the Teva
16 entities.

17 CHIEF JUDGE BUMB: Good morning.

18 MR. OSTFELD: Good morning, Your Honor. Greg Ostfeld
19 also from Greenberg Traurig. I also represent the Teva
20 entities.

21 CHIEF JUDGE BUMB: Good morning.

22 MS. DAVIDSON: Good morning, Your Honor. Jessica
23 Davidson, Skadden, Arps, on behalf of the ZHP Defendants.

24 CHIEF JUDGE BUMB: Okay. Good morning.

25 MS. COGHLAN: Good morning, Your Honor. Maureen

1 Coghlan of Archer & Greiner on behalf of the Mylan defendants.

2 CHIEF JUDGE BUMB: Good morning.

3 MR. TRISCHLER: Good morning, Your Honor. Clem
4 Trischler also appearing on behalf of the Mylan defendants.

5 CHIEF JUDGE BUMB: Good morning.

6 MR. HARKINS: Good morning, Your Honor. Steven
7 Harkins, also with Greenberg Traurig on behalf of the Teva
8 defendants.

9 CHIEF JUDGE BUMB: Good morning.

10 Anyone else?

11 MR. LAVELLE: Good morning, Your Honor. John
12 Lavelle, from Morgan Lewis, on behalf of Aurobindo.

13 CHIEF JUDGE BUMB: Okay. Good morning.

14 Do you folks want a seat at the table? We could
15 bring maybe -- I hate to have you all sit back there.

16 MR. BERNARDO: Good morning, Your Honor. I will also
17 introduce myself. I'll be addressing one argument. Richard
18 Bernardo from Skadden, Arps, also for the ZHP Defendants. And
19 for efficiency, I have with me Zachary Martin and Alex
20 Kasparie, also from Skadden, Arps for the ZHP defendants.

21 CHIEF JUDGE BUMB: Okay. Good morning.

22 Does anyone wish to sit up here?

23 MR. BERNARDO: We're fine back here, if that's okay,
24 Your Honor.

25 CHIEF JUDGE BUMB: Okay. So if you do want to speak

1 up, I'm hard of hearing, so if you can shout just a little,
2 okay.

3 MR. BERNARDO: I'm assuming that during my argument I
4 will come up, if that's okay.

5 CHIEF JUDGE BUMB: Okay. That's fine. That's fair.

6 Okay. All right. Well, nice to meet you all. Nice
7 to get to know you all. We'll be together for a while. I know
8 Judge Vanaskie is on his way, so it would be good to have him
9 joining us.

10 So you've all kept me a little busy. I ask for your
11 patience.

12 So a couple of things I wanted to say. If we could
13 just change the way we've been doing things, I work from the
14 docket, strictly from the docket. So I want everything filed
15 on the docket. Anything that has to be sealed or redacted, I
16 want it filed on the docket. So you'll just file your
17 redactions. You'll file your motions to seal. So I can only
18 strictly work from the docket.

19 I know that in the past there has been some emails to
20 the law clerk, et cetera, forwarding the redactions. It's much
21 easier for me to work strictly from the docket. Any questions
22 about that?

23 (No response.)

24 CHIEF JUDGE BUMB: No? Okay. Good.

25 And then if there's thumb drives or that, then

1 they'll just be sent directly to chambers.

2 So I received the agenda.

3 MR. STANOCH: Your Honor.

4 CHIEF JUDGE BUMB: Yes.

5 MR. STANOCH: David Stanoch for plaintiffs. How are
6 you?

7 CHIEF JUDGE BUMB: Good morning.

8 MR. STANOCH: Just a question about your ECF
9 procedures for sealing.

10 CHIEF JUDGE BUMB: Yes.

11 MR. STANOCH: Would Your Honor expect motions to seal
12 every time either side files provisionally under seal? Because
13 so far we have not done that, and we could do that. It's just
14 procedurally --

15 CHIEF JUDGE BUMB: That's a lot.

16 MR. STANOCH: It's a lot of motions to seal.

17 CHIEF JUDGE BUMB: It's a lot of work. And I don't
18 think it's necessary. So what I would propose is come up with
19 a resolution. Either work with Judge Vanaskie or come up with
20 an agreement. You'll file your motion. You'll file what --
21 you'll file your redacted motion on the docket. You'll file
22 your unredacted under seal. You will then file an omnibus
23 motion to seal at some point, okay? So you'll just collect
24 them all and you'll put forth reasons why your motion should
25 have been sealed or should be sealed.

1 MR. STANOCH: Very good. Thank you, Judge.

2 CHIEF JUDGE BUMB: Okay. So come up with a
3 resolution. You know, maybe once a month file -- I don't know.
4 Come up with a resolution. But definitely -- I thank you for
5 the question. Yeah. We don't need a motion every time.
6 That's a lot of work and not necessary.

7 MR. STANOCH: Thank you, Your Honor.

8 CHIEF JUDGE BUMB: Okay. So, you know, as I thought
9 about how to go forward, because I do, as I told you, I work
10 from the docket, how I can best help the parties.

11 There's a lot of -- I don't know if you want to call
12 it cleaning up or whatever to do. But I thought I would just
13 go right to the motions and just work through them, and then
14 I'll get to the motions in limine, which I've read through, and
15 I'll hear argument on that. We'll talk about the trial date.
16 But you folks tell me, is there something -- you want me to do
17 it in reverse order? You tell me.

18 MR. SLATER: I think that makes sense, Your Honor,
19 however -- I think that's a reasonable way to approach it.

20 CHIEF JUDGE BUMB: Do it that way?

21 MR. SLATER: Sure.

22 CHIEF JUDGE BUMB: Yes? Agreed?

23 MS. ALLON: Yeah. That's good with us, Your Honor.

24 CHIEF JUDGE BUMB: Yeah. So the first motion is
25 2641, right? It involves the Meridan report. That's how I see

1 it in my docket.

2 MS. ALLON: So, Your Honor, we're happy to start
3 there. The way we did the motions in limine is we have a set
4 of motions in limine that are common --

5 CHIEF JUDGE BUMB: Yeah.

6 MS. ALLON: -- across all defendants and all
7 plaintiffs. And then we have a subset of defendant-specific
8 motions in limine.

9 CHIEF JUDGE BUMB: Yeah.

10 MS. ALLON: And I think the one you identified is the
11 first of the Torrent-specific motions in limine.

12 CHIEF JUDGE BUMB: Yeah.

13 MS. ALLON: Now, I'm more than happy to start there.
14 But I think two things. First of all, I think it may be more
15 efficient to start with the ones that are common to all the
16 parties.

17 And in our letters, I believe both sides did identify
18 a subset of motions in limine that we thought would be the most
19 helpful in terms of getting guidance from the Court. So to the
20 extent we may not get to all of the motions in limine today --

21 CHIEF JUDGE BUMB: I think we will.

22 MS. ALLON: Okay. So would Your Honor prefer to
23 start with the defendant-specific ones or the ones that are
24 common?

25 CHIEF JUDGE BUMB: Well, I was just going to go in

1 numerical order. I'm going to give you my rulings today. And
2 my rulings might be one-liners. I don't know. You're just
3 going to get my rulings. But I think we're going to go through
4 everything -- not everything. I don't know about everything.
5 That's a little ambitious, but we're going to get quite far
6 along.

7 MS. ALLON: Okay. So I'm happy to start with Motion
8 in Limine No. 1, which is if that's what Your Honor --

9 CHIEF JUDGE BUMB: You call it Motion in Limine
10 No. 1. I call it Motion in Limine 2641.

11 MS. ALLON: Okay. Yes. That's the docket number,
12 2641.

13 CHIEF JUDGE BUMB: Yeah.

14 MS. ALLON: Yeah.

15 CHIEF JUDGE BUMB: So if we can work from docket
16 numbers, I'm very confused about the -- when you folks talk
17 about MIL-1, 2, 3, 4. That's very confusing to me. I might
18 get there. But I'm now looking at 2641. It's a motion in
19 limine. It's Torrent specific. It's a motion in limine
20 regarding the Meridan report.

21 MS. ALLON: That's right, Your Honor.

22 CHIEF JUDGE BUMB: Okay. So I'm just going to cut to
23 the chase. I don't think the Meridan report comes in. You're
24 not going to tell me why, because you already have.

25 MS. ALLON: That's right, Your Honor.

1 CHIEF JUDGE BUMB: So let me hear from plaintiffs.

2 MR. NIGH: Your Honor, we would think the Meridan
3 report comes in, but you've probably read the arguments to an
4 extent. I don't know if you have any questions for me. But
5 the reason we would think the Meridan report comes in is it
6 shows all the different testing --

7 CHIEF JUDGE BUMB: Yeah.

8 MR. NIGH: -- and broadly the mistakes that were
9 being done by Torrent in their testing procedures, which we
10 think bleeds over to this overall issue that Torrent had sloppy
11 testing procedures, and that's why they also weren't able to
12 find NDMA because they weren't testing for it.

13 CHIEF JUDGE BUMB: But how does the jury figure out
14 which ones were compliant and which ones weren't? Aren't you
15 just sort of throwing it up against the board and saying, well,
16 they were just sort of sloppy and therefore -- and therefore,
17 you know, they should be found liable? Isn't that the problem?

18 (Judge Vanaskie entered the courtroom.)

19 CHIEF JUDGE BUMB: Welcome, Judge Vanaskie.

20 JUDGE VANASKIE: Good morning. Sorry I'm late.

21 CHIEF JUDGE BUMB: Good morning.

22 MR. NIGH: That's a good question, Your Honor. I
23 think the ones that would be most relevant, if we were looking
24 at ones that would be relevant, certain redactions to the
25 report -- that's another question -- but the ones that would be

1 most relevant would be those where they found out of spec,
2 meaning that the testing showed that the product wasn't met --
3 didn't meet specifications.

4 CHIEF JUDGE BUMB: Right.

5 MR. NIGH: So when they had out-of-spec
6 specifications, and then Torrent just ignored those out-of-spec
7 specifications and sold it anyways, or they just simply ignored
8 the out of spec, retested it, had a finding that they liked,
9 and then sold it anyways.

10 Had they actually investigated those out-of-spec
11 findings the same way that the finished-dose manufacturer that
12 shown light on this, Novartis, had they tested it the same way
13 Novartis had tested it, Novartis found out of spec, they tested
14 to see what the peaks were. They saw the peaks, then they
15 identified what those peaks were and that's how they found
16 NDMA.

17 So the very first step is an out-of-spec finding and
18 actually doing the investigation to figure out what that
19 out-of-spec finding is.

20 CHIEF JUDGE BUMB: But how does a jury figure out,
21 well, they did it for this drug and they didn't do it for that
22 drug? Because the Meridan report shows that they were
23 compliant for several of the drugs. They were mostly compliant
24 or not compliant. That was what the finding was. So how does
25 a jury figure out -- because it seems to me it's going to be a

1 trial within a trial with respect to which product was being
2 tested, and then you're going to ask the jury, call upon the
3 jury to make a determination whether or not that procedure is
4 most likely the closest to the procedure that should have been
5 followed with valsartan. How does a jury do that?

6 Because they're going to get up and say -- they, the
7 defendants, are going to get up and say, well, no, they were
8 compliant for procedures that were like valsartan. Look at the
9 Meridan report. And then it becomes really a trial all about
10 the Meridan report and what it stands for.

11 MR. NIGH: Yeah. I don't think it goes that far. I
12 think it shows the very first step. And I don't agree that
13 they were mostly compliant with most drugs. In fact, what we
14 see is widespread across the majority of them, they have this
15 out-of-spec problem across, you know, nearly every single drug
16 that they manufacture at that facility.

17 CHIEF JUDGE BUMB: Well, I don't know. I mean, I'm
18 looking at the report. It seems half were mostly compliant and
19 half weren't.

20 MR. NIGH: Well --

21 CHIEF JUDGE BUMB: Let me hear from your adversary.

22 MS. ALLON: Thank you.

23 MR. NIGH: Judge, can I give one more piece to that?

24 CHIEF JUDGE BUMB: Yes. Of course.

25 MR. NIGH: Out of compliant would mean there are many

1 times that they test the product and it's not out of spec.

2 CHIEF JUDGE BUMB: Say it again.

3 MR. NIGH: There are times that they test the product
4 and it's not out of specification.

5 CHIEF JUDGE BUMB: Right.

6 MR. NIGH: That doesn't mean across drugs that they
7 don't have out-of-spec problems. They have it across all of
8 the drugs that they manufactured at that facility.

9 CHIEF JUDGE BUMB: No. But I guess the question that
10 you haven't really answered for me is, how is a jury to
11 determine with respect to which procedure was being followed
12 with respect to this drug?

13 MR. NIGH: The testing procedure on how they follow
14 up on out of specifications is the issue. And the issue is
15 when they have out of specifications across all their drugs,
16 they don't do the adequate follow-up on how they should test
17 out of specification. That's what the Meridan report stands
18 for.

19 CHIEF JUDGE BUMB: Do you agree with that?

20 MS. ALLON: No, I don't agree with that, Your Honor.

21 The Meridan report covers an entirely different issue
22 than the one that's at issue in this case. It covers
23 out-of-specification results. There is not an allegation from
24 the plaintiffs that somehow Torrent violated cGMP by not
25 following out-of-specification results.

1 Their argument is that we violated cGMP because we
2 didn't do the right testing to find the nitrosamines.

3 CHIEF JUDGE BUMB: That's how I understood it.

4 MS. ALLON: Right. And that's not implicated by the
5 report for a couple of reasons. Number one, like I said, the
6 report is out-of-specification results.

7 Number two, the report doesn't cover valsartan, which
8 is the product at issue in this case.

9 And number three, the report was done over a year
10 after the recall. So it is a complete sideshow. As Your Honor
11 noted, it is going to devolve into a trial within a trial. At
12 our corporate representative's deposition, there's 40 pages of
13 questioning on this report speculating that maybe it's somehow
14 related to the drugs at issue in this case. And that is what
15 is going to happen if it's admissible in this trial. It's
16 confusing to the jury and it's unduly prejudicial.

17 CHIEF JUDGE BUMB: All right. The Meridan report is
18 not in. I'll grant that motion. I think for the reasons I've
19 been articulating, it was a year after the recall. It doesn't
20 involve valsartan. I do think it will devolve into a mini
21 trial within a mini trial. I think under 401, I don't think it
22 is relevant, in the sense that it's likely to lead to evidence
23 that will be helpful to the jury. I think it will be more
24 confusing.

25 Okay. So that's only one part of your motion.

1 What's the other part? Let's go through them.

2 MS. ALLON: Yes, Your Honor. The next one is --

3 CHIEF JUDGE BUMB: References to "cheap" versus
4 "cheaper."

5 Well, it is what it is. I mean, whatever the email
6 used is what should be said.

7 MS. ALLON: Right. And I think that's the
8 distinction. The email says "cheaper." The plaintiffs
9 routinely say "cheap." Those two things are not the same.

10 CHIEF JUDGE BUMB: Okay. So the evidence will be
11 "cheaper."

12 Okay. What about evidence and argument that
13 Torrent's actions were financially motivated?

14 That's a jury question.

15 MS. ALLON: Well, Your Honor, the problem is that the
16 sentence that they rely on for this proposition wasn't authored
17 by a Torrent employee. It was authored by somebody from ZHP.
18 And so the attempt to impute that because it was in an email
19 chain, which Torrent participated, to Torrent, is quite
20 misleading and confusing.

21 CHIEF JUDGE BUMB: But that's why it's a jury
22 question. That's the argument you will make. You will make
23 that argument to the jury. You will say that that was not an
24 admission or a statement that was adopted by Torrent; that it
25 was strictly ZHP. That becomes a jury question, not a Court

1 question, right?

2 MS. ALLON: I think that's right, Your Honor.

3 But I think if we all agree that that sentence isn't
4 attributed to Torrent -- and it's clearly not -- there's no
5 basis in the record for even making the argument that Torrent
6 was financially motivated with respect to this particular issue
7 of when it did the recall. If they want to make arguments
8 about other financial motivations, they're free to do so, but
9 when they were --

10 CHIEF JUDGE BUMB: So are you saying that there's no
11 evidence in the record for which a jury might reasonably
12 conclude that it was a statement adopted by ZHP -- I mean by
13 Torrent?

14 MS. ALLON: That's right, Your Honor. And I don't
15 think the plaintiffs have pointed to any.

16 CHIEF JUDGE BUMB: Okay. Let me hear about that.

17 MR. NIGH: Your Honor, that couldn't be further from
18 the truth. In fact, there's been countless deposition
19 testimony on this issue. There are numerous documents that
20 Torrent has where their quality control person says we need to
21 test our products, we need to test our product to see if it
22 actually has NDMA. And they don't test their product. They
23 wait for the FDA to do it.

24 But on the same day that the quality director is
25 saying "we need to test our product," the CFO weighs in, takes

1 the quality control person off -- it's on the same email
2 chain -- takes the quality control person off and says "how
3 much are we going to get in supply penalties? How much do we
4 have in inventory? How much money can we make from this? How
5 much profit did we get in the last couple quarters?" There's
6 all sorts of information that shows they're financially
7 motivated.

8 CHIEF JUDGE BUMB: Yeah. But that wasn't the
9 question I think we were focused on. Is there evidence that
10 the statement that was made by ZHP, that that was adopted by
11 Torrent? Or is there other evidence that the plaintiff is
12 relying upon to show that Torrent was financially motivated?

13 MR. NIGH: Well, they received that information
14 itself too. They're on that. They received that information.
15 So how to decide if they officially adopted it, I think it goes
16 along with ZHP knew their product was cheap, they knew it was
17 much cheaper than the rest of the product out there.

18 CHIEF JUDGE BUMB: Cheaper, yeah.

19 MR. NIGH: And Torrent also knew that -- well, the
20 reason we've said "cheap," this all came into play in the first
21 place because their own deponent said -- was using the word
22 "cheap." That's how the whole thing started.

23 So, but --

24 CHIEF JUDGE BUMB: Well, so to be clear, what my
25 ruling is, is that it will not be misquoted. The email said

1 "cheaper," didn't it?

2 MS. ALLON: Yes.

3 MR. NIGH: It does say "cheaper."

4 CHIEF JUDGE BUMB: So that will be what the jury will
5 hear. We're not going to mislead the jury and say it said
6 cheap. "Cheaper."

7 MR. SLATER: But it's the deponent who's quoting
8 "cheap" in response. So that is evidence in and of itself.
9 It's their deponent using the word "cheap."

10 CHIEF JUDGE BUMB: Okay. So whatever it is, you'll
11 be quoting it accurately, that's all.

12 MR. NIGH: Yes. Understand.

13 CHIEF JUDGE BUMB: Okay.

14 MR. NIGH: To my point, financial motivation is all
15 throughout here. That's one example on that MIL. Their
16 further -- their further expectation on this MIL is to try to
17 exclude all evidence related to this financial motivation.

18 CHIEF JUDGE BUMB: It's a jury question. That's my
19 ruling.

20 MR. NIGH: Thank you, Your Honor.

21 CHIEF JUDGE BUMB: Okay. All right. Evidence and
22 argument that Torrent should have recalled its VCDs in June of
23 2018.

24 I think it's a jury question. You want to persuade
25 me differently, Ms. Allon.

1 MS. ALLON: I mean, I'll try, Your Honor.

2 I think that under 403, the argument is misleading
3 because it's contradicted by the record. And relevant to that
4 is, it is unfair and inflammatory. We're not saying that
5 evidence of a delayed recall is always, you know, per se
6 subject to exclusion. But in this situation, where there's no
7 evidence of it in the record, then it becomes unfairly
8 prejudicial. And the plaintiffs again don't point to evidence
9 in the record that the recall was in any way delayed.

10 They say that -- they list dates that they say
11 Torrent supposedly ignored. I don't have to go through all the
12 dates. But the point is, what they don't dispute is Torrent
13 was in constant communication with the FDA to determine when it
14 should conduct the recall. As soon as the FDA told it to
15 conduct the recall, it did. There was no delay. There's no
16 evidence of delay. And in that situation, arguing that
17 essentially the recall was delayed is prejudicial.

18 CHIEF JUDGE BUMB: It didn't seem there was a delay.
19 What are you hanging your hat on?

20 MR. NIGH: Well, there's clearly a delay, Your Honor.

21 In June of 2018 --

22 CHIEF JUDGE BUMB: Yeah.

23 MR. NIGH: -- ZHP let them know that their product
24 may have genotoxins in it; that their API has genotoxins.

25 At that time we were also seeing the FDA telling

1 Torrent they need to be testing their product. They told every
2 manufacturer they need to test their product. Torrent took
3 forever to test their product. All the rest of these
4 defendants figured out how to get their product tested before
5 Torrent ever did.

6 And the other part, they continue -- they also like
7 to point to this statement that comes back from ZHP saying
8 their product is free of genotoxins. That comes back later,
9 before the recall as well, and that's all -- and they say --
10 ZHP says it's free of genotoxins, we can fully rely on that
11 statement.

12 Well, that's absurd, as we pointed out. One, it's
13 because they were also selling new product in Europe, new
14 processed valsartan in Europe that was supplied by ZHP, where
15 ZHP had told them that was free of genotoxins back in 2015.
16 And it was wrong. So to blindly, for the second time, rely on
17 ZHP a second time is inadequate.

18 Now, it's not just delayed recall. That's the way
19 Torrent likes to try to set up this argument; that that's all
20 we're arguing. It is delayed testing. It is, you know,
21 burying the head in the sand and not finding out if they had an
22 issue. It's not asking ZHP to test the products and just let
23 us know if it's got NDMA. Test whole process. Let us know if
24 it has NDMA. They didn't want that answer, because you know
25 what happened? The FDA, when they inspected ZHP, and they

1 asked -- the FDA inspector in August of 2018 asked ZHP is there
2 any NDMA in old process, and ZHP said, no. Jun Du says, no,
3 there's no NDMA. And the FDA inspector says, well, have you
4 actually tested it? And ZHP says, no, we actually haven't
5 tested. We haven't tested it. The FDA inspector says, please
6 test the products.

7 Lo and behold, the very next day, it took one day,
8 ZHP comes back and says, oh, it actually does have NDMA, we
9 were wrong.

10 All Torrent had to do was ask ZHP to test that
11 product when they received the statement back in June of 2018,
12 let us know if it really is in old process. Within one day
13 they could have had that answer.

14 MS. ALLON: What the plaintiffs are leaving out is
15 there wasn't a testing method for NDMA. The plaintiffs are
16 saying there was one choice, test and then do a recall.

17 Well, Torrent did test. It had to develop a testing
18 method. Remember Torrent didn't have one and the FDA didn't
19 have one. And ZHP's notification didn't say which batches were
20 affected or in what quantity. And so Torrent did work on a
21 testing method that it had to build and validate and employ.

22 But importantly, on July 16th, July 16, 2018, the FDA
23 greenlit our selling of valsartan. The FDA continued to say
24 that we can sell our product.

25 On August 16, 2018, for the very first time, the FDA

1 confirmed to us that there was nitrosamine in our product, and
2 we instituted our recall the next day, August 17th. It is
3 impossible to believe that August 16th to
4 August 17th constitutes a delay.

5 CHIEF JUDGE BUMB: Yeah. I think it's in how the
6 parties are framing the issue. So Torrent is framing it as a
7 delay in issuing the recall.

8 The plaintiffs are framing the issue as a delay in
9 doing the testing necessary for the recall to happen sooner.

10 So it's a jury question.

11 Okay. Next is evidence and argument that Torrent did
12 not address the concerns raised by Dr. Yang should be excluded.

13 I think this is clearly a jury question for the
14 similar reasons. And I don't need argument on that.

15 Okay. So granted in part, denied in part.

16 I think I covered them all, right?

17 MS. ALLON: Yes, Your Honor.

18 CHIEF JUDGE BUMB: Okay.

19 MR. NIGH: Yes, Your Honor.

20 CHIEF JUDGE BUMB: Okay. Next one, 2644. This is a
21 motion in limine, Teva defendants omnibus motion. 2644, let's
22 go to this. This is the -- I think it's the Toxikon report.

23 MS. LOCKARD: Correct, Your Honor.

24 CHIEF JUDGE BUMB: Okay. Let me hear you on this. I
25 don't think this -- well, let me hear you.

1 MS. LOCKARD: Yes. And I'll be addressing a portion
2 of these, and my colleague, Steve Harkins, will be addressing a
3 portion of Teva's motions.

4 CHIEF JUDGE BUMB: Okay.

5 MS. LOCKARD: As to the Toxikon report, Your Honor,
6 back in 2014, Teva contracted with a third-party company to do
7 some testing to look at extractible nitrosamines from a rubber
8 stopper package, packaging, on a drug, not valsartan, not at
9 issue in this litigation, totally unrelated.

10 CHIEF JUDGE BUMB: Remind me when it happened.

11 MS. LOCKARD: There was a known issue in the rubber
12 industry that rubber products could contain nitrosamines.

13 CHIEF JUDGE BUMB: This is before the recall, right?

14 MS. LOCKARD: This was way before the recall, four
15 years before the recall.

16 CHIEF JUDGE BUMB: Yeah. Uh-huh.

17 MS. LOCKARD: So when the plaintiffs searched through
18 Teva's documents for any reference to "nitrosamines" prior to
19 the recall, this was the sole document they found related to
20 any alleged knowledge of Teva knowing about nitrosamines.

21 The problem is that knowledge that there may be
22 nitrosamines in a rubber bottle stopper, which was known in the
23 rubber packaging industry, is not probative of whether Teva
24 knew that manufactured drugs, API finished dose, can have
25 nitrosamines. Totally different testing. It's a totally

1 different analysis. And it's totally different product. And
2 therefore we think it is a diversion, a waste of time, and it
3 should be excluded.

4 CHIEF JUDGE BUMB: Okay. What else is in your
5 motion? Let's see, is that the only motion? No. We've got
6 more.

7 MS. LOCKARD: We have more.

8 CHIEF JUDGE BUMB: Okay.

9 Well, you can talk to me about the Toxikon report,
10 but who's going to -- yeah.

11 MR. STANOCH: Your Honor, may I approach?

12 CHIEF JUDGE BUMB: You may.

13 I think it's the same issue with like the Meridan
14 report. I think we delve into -- I think the jury is going to
15 be saying to themselves why are we hearing about rubber
16 stoppers? So you can -- give it your best shot.

17 MR. STANOCH: Of course, Your Honor. I appreciate
18 that. I would only add two things. One is, and we've cited to
19 Teva's expert reports. Their defense at trial is: Nobody knew
20 about NDMA. NDMA is not that dangerous. Testing methods
21 didn't exist until we all rushed post recall to come up with a
22 testing method.

23 This document from 2014, pre-recall, rebuts all of
24 those. It shows --

25 CHIEF JUDGE BUMB: If they got up and said that

1 nobody ever heard of nitrosamine, is that what you're saying?

2 MR. STANOCH: That's one thing. If they say -- if
3 they disagree that nitrosamine, NDMA, is dangerous or unwanted,
4 this rebuts that. Because it says -- this document says that
5 it's an unwanted dangerous substance.

6 Number two, part of their argument of the defense is
7 testing methods didn't exist to find NDMA until after the
8 recalls.

9 This document rebuts that argument, Your Honor. It
10 shows that the capabilities and methods, the same methods, the
11 LC and MS testing that was eventually used on valsartan to find
12 NDMA, that's what's being used in 2014 to detect NDMA in the
13 stoppers.

14 CHIEF JUDGE BUMB: Now, let me ask this question: Is
15 it the same testing?

16 MS. LOCKARD: No, Your Honor. It's vastly different
17 testing. In fact, we had to develop testing for the
18 medications and for the API in the finished dose and validate
19 those.

20 CHIEF JUDGE BUMB: And are you going to stand up and
21 say nobody ever heard of nitrosamine?

22 MS. LOCKARD: No, Your Honor. We will say -- the
23 knowledge issue is as to whether there was knowledge that it
24 could form in the medication product. There's --

25 CHIEF JUDGE BUMB: Okay. So if you get up and say

1 anything like "nobody ever heard of nitrosamine" or open the
2 door, then it's fair game for cross. Otherwise, it doesn't
3 come in. I think it goes too far afield, for the same reason.

4 MR. STANOCH: Okay, Your Honor.

5 CHIEF JUDGE BUMB: Okay. The next part of the motion
6 is?

7 MS. LOCKARD: The next motion relates to a health
8 hazard assessment that Teva prepared once they knew about the
9 nitrosamine issue.

10 CHIEF JUDGE BUMB: Yeah.

11 MS. LOCKARD: This is, in some part, dependent on
12 other motions in this case.

13 CHIEF JUDGE BUMB: Okay.

14 MS. LOCKARD: Because plaintiffs have taken the
15 position that general causation and whether or not nitrosamines
16 in the amounts found in these drugs can cause or lead to a risk
17 of cancer. They think that should be out of the TPP case.

18 Our position is if --

19 CHIEF JUDGE BUMB: Well, I'm not going to -- I'm not
20 going to keep you all waiting. I think the plaintiffs probably
21 are right. But we can talk about it.

22 MS. LOCKARD: Well, we -- we certainly are prepared
23 to discuss that issue as well.

24 CHIEF JUDGE BUMB: Yeah. Yeah.

25 MS. LOCKARD: As for the HHA, if there is no general

1 causation evidence in this case and we're not talking about the
2 risk or the likelihood of cancer developing, then the HHA
3 should come out as well. It's not relevant. There's a lot of
4 prejudicial information.

5 CHIEF JUDGE BUMB: I think she's right. What do you
6 say?

7 MR. STANOCH: I disagree, Your Honor. I think that
8 this is a --

9 CHIEF JUDGE BUMB: Well, you can't have it both ways.

10 MR. STANOCH: I agree. I hear what you're saying,
11 and I appreciate what you're saying on general causation. But
12 the HHA goes beyond that.

13 CHIEF JUDGE BUMB: How so?

14 MR. STANOCH: The HHA, this is a contemporaneous
15 business document from the summer of 2018 specifically looking
16 about the NDMA in Teva's valsartan that was subject to the
17 recall. And putting aside general causation, which I agree
18 with you if that's going to go out, then part of it might not
19 be appropriate for this document. But there's a number of
20 facts in this document that don't go to the causation issue.

21 It says, for instance, NDMA was found in ZHP's
22 valsartan API; that NDMA is not approved in the specifications
23 or monographs; that of the 51 batches of ZHP valsartan API
24 initially tested, all of it found NDMA.

25 How did they find it? They detected it through gas

1 chromatography-mass spectrometry, GCMS. It talks about the
2 results of the NDMA.

3 CHIEF JUDGE BUMB: Okay. I'm kind of losing you. So
4 what part of it do you think is relevant assuming the general
5 causation issue that we have been discussing, it goes the way
6 the plaintiffs want it to go?

7 MR. STANOCH: The only other part I'd say, putting
8 that aside, is it shows that NDMA was present in Teva's
9 product, because it's -- all of the testing by the methods used
10 found ranges 3 to 120 parts per million with an average of 66
11 ppm. So it's reporting the actual testing results.

12 CHIEF JUDGE BUMB: Okay. Do you agree with that,
13 Ms. Lockard?

14 MS. LOCKARD: Your Honor, I do not.

15 CHIEF JUDGE BUMB: Do you agree with that particular
16 part?

17 MS. LOCKARD: No.

18 CHIEF JUDGE BUMB: Why?

19 MS. LOCKARD: Surprisingly. I believe there are many
20 other sources that will offer the same evidence which will be
21 cumulative of this document.

22 CHIEF JUDGE BUMB: Oh, that's a different argument.

23 MS. LOCKARD: So it is a different argument, but it's
24 an important one. Because he does not need to introduce this
25 prejudicial document and open a can of worms as to the safety

1 and how much of the nitrosamines --

2 CHIEF JUDGE BUMB: Here's my preliminary ruling then,
3 is if it's duplicative, it won't come in. It will be too
4 prejudicial, yeah. There's no need to bring it in. That's
5 preliminary. But I'll have to revisit the issue when we talk
6 about causation, okay? Fair enough.

7 MR. STANOCH: Yes, Your Honor.

8 CHIEF JUDGE BUMB: Okay. So let's turn to the --
9 Ms. Lockard, let's turn to the ANDA recision letter, re
10 Dr. Reddy. My notes ask myself why is this relevant, so you'll
11 tell me.

12 MS. LOCKARD: I asked myself the same question, and
13 the answer is it's not.

14 CHIEF JUDGE BUMB: Okay.

15 MS. LOCKARD: This is a product that was never
16 marketed. Teva never used Dr. Reddy's API. It's not relevant
17 at all. It's not at issue in this case. It was never sold in
18 the U.S.

19 The reason that the plaintiffs like this document is
20 because there's some, what I would call, "dicta" by the FDA
21 that basically says that, you know, just because a product is
22 in compliance with their specifications and the company is
23 doing testing, it doesn't mean that it's okay or that it's not
24 a problem.

25 But that is something that can be argued through

1 other documents and through other witnesses. And plaintiffs'
2 experts have already said this time and time again. So they
3 again have other sources for it.

4 To try to get into this Dr. Reddy's issue for an API
5 supplier that's not even a defendant in this case is going to
6 wildly confuse the jury, because they're going to say, well,
7 where is Dr. Reddy's product, and they don't need it.

8 MR. STANOCH: Your Honor, we say very clearly in our
9 briefing, we're not trying to prove anything about whether
10 there was NDMA or not in Dr. Reddy's API. This goes to Teva's
11 notice and knowledge.

12 Pre-recall, the FDA explicitly wrote Teva and said
13 for a facility to be in compliance with cGMP -- and recall our
14 allegations in part were that Teva was not in compliance with
15 cGMP -- it is not enough that the finished drug products,
16 Teva's products, or the APIs used to manufacture such finished
17 products, conformed to specifications and the testing for such
18 products.

19 So they want to argue we did all the spec testing.
20 We didn't see NDMA. No liability.

21 CHIEF JUDGE BUMB: Right.

22 MR. STANOCH: This is the FDA saying that's not
23 enough under cGMP.

24 CHIEF JUDGE BUMB: But your adversary is saying that
25 you have this in evidence elsewhere, elsewhere, elsewhere. You

1 don't?

2 MR. STANOCH: I disagree with that, Your Honor. It's
3 contested expert testimony, and we're entitled to present a
4 business record, public document, frankly, from the FDA to
5 Teva, and their experts -- my words, not hers, Ms. Lockard's --
6 I'd say twisted to avoid the literal language from the FDA in
7 this letter to avoid admitting it. It's a contested issue.
8 And I think we're entitled to cross their witnesses when we say
9 is it enough, Dr. So-and-so for Teva, that you did spec
10 testing, that means you must have been in cGMP compliance?
11 They're going to say yes, because I asked them multiple times
12 at deposition.

13 I should be entitled to show them this letter,
14 regardless of anything about Dr. Reddy's and the recision, to
15 say, well, the FDA told Teva in 2015 that that's not enough,
16 correct, Doctor? That's it.

17 MS. LOCKARD: Your Honor, what's happening is they
18 want to use this Dr. Reddy FDA letter as a bullhorn to make
19 their argument. It doesn't relate to nitrosamines. It doesn't
20 relate to nitrosamine testing. It doesn't relate to anything
21 to do with this case.

22 CHIEF JUDGE BUMB: But it counters an argument that
23 your experts have made, right? That's the point that the
24 plaintiffs want to use it for.

25 They want to be able to use this to show that Teva

1 was on notice that for a facility to be in compliance with
2 cGMP, it's not enough that the finished drug products conformed
3 to specifications. They want to be able to -- because the FDA
4 responded to that.

5 MS. LOCKARD: But we've never --

6 CHIEF JUDGE BUMB: And -- go ahead.

7 MS. LOCKARD: We have never said that that is the
8 only requirement; that we're only required to meet
9 specifications. We've said that is one requirement and that we
10 did. We've said we've met all of the rules, regulations and
11 guidances, that we've met with specifications and that we've
12 met the impurity guidances that are relevant to this case. So
13 it's not as if we're standing up and saying, well, all we have
14 to do is meet specifications, you know, we're out. If that
15 were the case, then I would, you know, grant the point.

16 CHIEF JUDGE BUMB: So fair enough. So if the door is
17 opened, if the argument is made, if the evidence is introduced
18 that Teva makes that argument that is directly contrary to what
19 the FDA pronounced in connection with the Dr. Reddy matter,
20 you'll be allowed to bring it in. But I'll require you to
21 somehow sanitize it. You're not going to talk about an ANDA.
22 You're not going to talk about a Dr. Reddy. It will have to be
23 somehow sanitized, because we're not going to get the jury far
24 afield in another ANDA application --

25 MR. STANOCH: Understood.

1 CHIEF JUDGE BUMB: -- with another manufacturer,
2 okay?

3 MR. STANOCH: Yes, Your Honor.

4 CHIEF JUDGE BUMB: So if the door is opened, I'll
5 revisit it.

6 Okay. The email chain I think is -- I think that's a
7 jury question. But go ahead.

8 MR. HARKINS: Your Honor, the reason that we don't
9 think that this should come in is simply because the product
10 that is at issue here does not relate to any product that is at
11 issue at trial. It does not even relate to product that is at
12 issue elsewhere in the litigation. This is about a facility on
13 which discovery was not conducted for a product that was never
14 marketed in the United States. Discovery into non-U.S.
15 products was not allowed under the Court's macro discovery
16 order. This is not an area of fact that has been developed.
17 It is a stray email discussion by a facility that, unless this
18 email is introduced, the jury is not going to be hearing about
19 Teva Israel and these products, which were never marketed in
20 the United States, were not manufactured or sold by the
21 defendants. This product was never purchased from ZHP. This
22 API was never used.

23 The validation and testing method that is being
24 discussed here has nothing to do with nitrosamines. It's just
25 going to require us to explain a bunch of other irrelevant

1 information to the jury while adding essentially nothing of
2 probative value. Because, again, this is not about any of the
3 products at issue. And the 2017 discussion would have had no
4 bearing on Teva's decision to use ZHP as an API supplier in a
5 different facility, manufacturing a different product for a
6 different market five years earlier.

7 MR. STANOCH: Jury question, Your Honor.

8 Teva was sourcing API from ZHP, which is part of this
9 trial, right, for the U.S. market. They were also sourcing it
10 from Mylan at their Israeli facility. And this email in 2017,
11 pre-recall, is about the Israeli's facility, which at the time
12 was using Mylan valsartan API to say maybe we, Israel facility,
13 should buy from ZHP, too.

14 Teva already is buying ZHP's valsartan API from the
15 Malta facility. So there's no this "silo" of them. This
16 facility was already subject to discovery. I disagree with
17 that because it was already sourcing Mylan API which is in this
18 case for the last six years.

19 But the point is, the people at Teva are saying we're
20 looking at maybe we should buy valsartan API from ZHP. And,
21 oh, my gosh, there's all these issues. Their report is not
22 convincing. They don't mark system peaks in terms of the
23 testing, right? And as I'm sure you know by now, Your Honor,
24 peaks in the chromatography is a big issue, and a number of
25 other things. Multiple explanation points about results,

1 basically saying this isn't good, we shouldn't get it.

2 So if Teva over here is buying it and Teva over here
3 is saying, no, this is not good, we think that's germane. The
4 jury can entitle whatever weight it wants. I don't think it
5 matters whether it's a product sold in the U.S. or not. This
6 is other Teva people looking at the same API saying, oh, we're
7 buying it over here at Malta, maybe we should do it in Israel,
8 and the Israelis say, oh, gosh, no, this is not good.

9 CHIEF JUDGE BUMB: I think it's a jury question.

10 MR. HARKINS: Understood, Your Honor.

11 CHIEF JUDGE BUMB: Okay. The Guda email, talk to me
12 about that.

13 MR. HARKINS: Your Honor, the Guda email is
14 another --

15 CHIEF JUDGE BUMB: You might as well talk about the
16 Karlsson email, and let's talk about those.

17 MR. HARKINS: Sure. Would you like me to address
18 them both --

19 CHIEF JUDGE BUMB: Yes, please.

20 MR. HARKINS: -- or Guda first.

21 So beginning with the Guda email, the Guda email is
22 going to be attempted to be introduced to suggest something
23 that there simply is no factual record of having occurred.
24 They're going to introduce a snippet of an email to argue that
25 it means Teva received a DMF from ZHP at a post-recall period

1 of time. That has no relevance to whether Teva after the
2 recall had the DMF, reviewed the DMF. And it's not appropriate
3 to suggest that based on receiving the DMF at this time, Teva
4 could or should have done something different in the pre-recall
5 universe. It's simply sort of an undeveloped piece of fact
6 that they want to throw in to try, without full factual
7 development, to suggest that Teva could have done something
8 earlier.

9 It doesn't say enough in the email about that. And
10 there's not enough factual record to explain it, again, without
11 introducing facts that simply aren't present in the trial yet.

12 CHIEF JUDGE BUMB: Why does it come in? Why does
13 that come in?

14 MR. STANOCH: Your Honor, one of Teva's and, frankly,
15 Torrent's, I think, in parts, arguments is that we as the
16 person purchasing API from ZHP, we can't see the DMF. It's
17 closed. You, plaintiffs, cannot say we should have looked at
18 the DMF more closely because we don't ask for it, we never look
19 at it, we don't even talk about it, right? And we cite their
20 experts, for example, and their fact witness saying DMF is
21 generally closed, and the contents are not disclosed, or saying
22 we do not have conversations with our API suppliers about the
23 DMF.

24 This rebuts that. In May 2018, a few weeks before
25 the recalls that are bringing us here today, Teva was saying to

1 ZHP about the valsartan API, send us -- make the DMF available
2 for the inspection coming up, and then they email back and say,
3 send us the DMF. And this email from ZHP's regulatory group --
4 and this is all a party opponent -- responds saying it's in the
5 mail, here's the tracking number.

6 So if they're going to get up and say, Your Honor, we
7 never look at the DMF, it's unreasonable for you to say that we
8 should have looked at it or even asked about it, in the
9 ordinary course, weeks before the recall, they did just that.

10 CHIEF JUDGE BUMB: What are you going to say about
11 that, Mr. Harkins?

12 MR. HARKINS: Your Honor, the fact that at some point
13 in time a finished-dose manufacturer may request and may be
14 able to obtain the DMF is not disputed. Teva has not taken a
15 position and will not take the position that they have never
16 seen that --

17 CHIEF JUDGE BUMB: Okay. But are you going to get up
18 and argue to the jury that we never request the DMFs?

19 MR. HARKINS: No, Your Honor.

20 CHIEF JUDGE BUMB: And it's not the practice to do
21 so?

22 MR. HARKINS: We will present and our experts have
23 presented testimony to the effect that it is not required, and
24 in the ordinary course there are closed portions of the DMF
25 that a finished-dose manufacturer does not routinely have

1 access to, not just with valsartan, with other drugs. And we
2 will make that argument.

3 CHIEF JUDGE BUMB: And you can make that argument.
4 And they can make the argument, but if you wanted it, you could
5 have gotten it, see this email.

6 So I think that if that's the door you open and
7 that's the testimony you present through your experts, it
8 does -- it seems to me that it's fair game for the plaintiffs
9 to respond, saying, sure, it's not required, but they could
10 have. And that becomes a weight issue for the jury.

11 MR. HARKINS: Understood, Your Honor.

12 CHIEF JUDGE BUMB: Okay. The next email.

13 MR. HARKINS: The Karlsson email is a subsequent
14 remedial measure. And that is our argument for excluding it.
15 In 2018, months after the recall, Stefan Karlsson, who is a
16 Teva employee in the research and development department, not
17 the quality department of Teva that oversees DMF review, made
18 some internal recommendations after the nitrosamine issue was
19 known, the recall had been initiated. The valsartan product
20 was off the market, and he made some internal recommendations
21 about how Teva could improve its DMF review process internally.
22 This was not a function of his job. It is not something he was
23 assigned to do. It is an internal email from an interested
24 employee making his own comments after the recall about what
25 they could do better going forward. We think it's a subsequent

1 remedial measure, and there are any number of relevance issues
2 with this particular witness being relied on to make that
3 point.

4 MR. STANOCH: Your Honor, this is not just any
5 employee. This was one of Teva's API procurement personnel
6 who's been procuring API for multiple decades by the time of
7 this email.

8 In fact, Mr. Karlsson was at a conference in China in
9 June 2018 when news of this issue started surfacing and he went
10 over and talked to ZHP at their booth at the convention. He
11 was also tapped eventually --

12 CHIEF JUDGE BUMB: This is post recall?

13 MR. STANOCH: Well, this is pre-recall, in June 2018.

14 CHIEF JUDGE BUMB: Pre-recall, okay.

15 MR. STANOCH: Because the recall happened in July.

16 CHIEF JUDGE BUMB: Okay. And what did he talk about?

17 MR. STANOCH: Well, I'm just setting the stage that
18 he's not just any employee; that he has direct percipient
19 knowledge, and he was also --

20 CHIEF JUDGE BUMB: I know. But what is the
21 knowledge? What's the evidence of the knowledge? Did he just
22 chit-chat or what was the --

23 MR. STANOCH: Well, the issue with his email is he's
24 talking to other Teva personnel about Teva's existing practices
25 at the time prior to the recall.

1 CHIEF JUDGE BUMB: Yes.

2 MR. STANOCH: Saying when we source API, we are not
3 doing A, B, C, D and E. We don't have a team that specializes
4 in API matters in DMF review. We do not use DMF reviewers,
5 which, by the way, goes to --

6 CHIEF JUDGE BUMB: And that's all state of the
7 company at the time.

8 MR. STANOCH: At the time, correct.

9 CHIEF JUDGE BUMB: There's no dispute about that,
10 right?

11 MR. HARKINS: Your Honor --

12 CHIEF JUDGE BUMB: That part of the email, there's no
13 dispute about that.

14 MR. HARKINS: Your Honor, the content in the email
15 about what Teva's practices were at the time --

16 CHIEF JUDGE BUMB: That's not disputed.

17 MR. HARKINS: -- we are not disputing that.

18 CHIEF JUDGE BUMB: Okay. Go ahead.

19 MR. STANOCH: Oh. That takes a very large part of
20 it. And then in terms of --

21 CHIEF JUDGE BUMB: Right. But then the part that
22 they seek to exclude is now, having had the benefit of
23 hindsight, here's what we should be doing.

24 MR. STANOCH: Uh-huh. And that's really not a true
25 subsequent remedial measure for the number of reasons we cite

1 in our briefing.

2 CHIEF JUDGE BUMB: But I do think it's prejudicial.
3 I think it's to -- now that all of this has come to the
4 forefront, in retrospect this is what we should have done, I do
5 think under a balancing of 403, it's too prejudicial. So I'll
6 exclude that part of the email.

7 MR. STANOCH: Okay. Thank you, Your Honor.

8 CHIEF JUDGE BUMB: Okay. What's the next part?

9 MS. LOCKARD: The next one, Your Honor, relates to
10 Teva's SOP. It's a corporate policy. It's number 00046. It's
11 a diversion. This is a policy that relates to no one at issue
12 in this case, to none of the defendants. It is a contract
13 manufacturer policy. These drugs were not made under contract
14 manufacturing. Contract manufacturing would be as if Teva
15 said, you know, we're going to take ZHP's API, we want you to
16 manufacture the finished dose for us, third party, and you're
17 going to be our contract manufacturer and then we'll put our
18 label on it and then we'll send it out. That is not what
19 happened in this TPP case in the drugs at issue.

20 CHIEF JUDGE BUMB: Yeah. Why is this relevant,
21 Mr. Stanoch?

22 MR. STANOCH: Your Honor, they ran away from their
23 own SOP. This SOP says the manufacturer at issue is any
24 firm -- any firm -- that provides drug product or processes a
25 drug product or drug substance.

1 The API being sourced from ZHP, that's a drug
2 substance. So they're saying this doesn't apply, but the
3 actual words of the policy say it does apply.

4 CHIEF JUDGE BUMB: But tell me why it's relevant.

5 MR. STANOCH: Because the SOP sets forth the criteria
6 that Teva itself should be following and overseeing suppliers
7 of API.

8 There are other criterion here saying what you should
9 be doing in terms of oversight for cGMP compliance. And they
10 want to say, oh, well, they weren't a contract manufacturer, so
11 SOP doesn't apply.

12 We disagree with that because it states on its face
13 it applies to anyone who's making a drug product or drug
14 substance.

15 And further, their 30(b)(6) witness said that they
16 expect the same cGMP expectations whether it's an API
17 manufacturer who's a contract manufacturer or not.

18 CHIEF JUDGE BUMB: I'm kind of losing maybe both of
19 you.

20 Are you saying that this does apply and they're
21 saying it doesn't apply?

22 MR. STANOCH: Yes. I'm saying it applies.

23 CHIEF JUDGE BUMB: But they're saying it doesn't
24 apply. How do we resolve this? Because I'm not going to have
25 a jury resolve whether or not this contract supplier

1 language --

2 MS. LOCKARD: Our 30(b)(6) witness who was questioned
3 on this, Dan Barreto, was asked about this, and he said it
4 doesn't apply to ZHP in this context. It applies to contract
5 manufacturers. Teva has a different and maybe even a
6 heightened interest when they're further removed from a
7 contract manufacturer. There are different SOPs that relate to
8 suppliers like ZHP.

9 CHIEF JUDGE BUMB: What evidence do you have,
10 Mr. Stanoch, that it applies?

11 MR. STANOCH: The evidence --

12 CHIEF JUDGE BUMB: Their 30(b)(6) witness said no.
13 What evidence does the plaintiff have that that's not true?

14 MR. STANOCH: It would be the policy itself, Your
15 Honor.

16 CHIEF JUDGE BUMB: No. Okay. Now we're too far
17 afield. It's too far afield. We're not going to have a jury
18 decide that.

19 If you had evidence to refute their 30(b)(6) witness,
20 you know, I would listen to you. But we're not going to have a
21 jury decide that if you don't have that evidence.

22 Okay. What's the next one?

23 MR. HARKINS: Your Honor, the next issue relates to
24 references to Teva's TAPI, or the Teva API division.

25 CHIEF JUDGE BUMB: Okay.

1 MR. HARKINS: And we sought to exclude references to
2 TAPI.

3 No API manufacturer by this division of Teva is at
4 issue anywhere in this litigation. It is not at issue for
5 purposes of the trial involving ZHP's API. It is not at issue
6 for purposes of Teva product manufactured using Mylan API,
7 which is not at issue in this trial, but has been subject to
8 discovery in this litigation.

9 This entity has not been the subject of discovery
10 because the Court's macro discovery order did not allow
11 discovery into entities such as TAPI that did not manufacture
12 at-issue API that was used for any of the products at issue in
13 this litigation. This creates a separate trial of Teva needing
14 to explain --

15 CHIEF JUDGE BUMB: We got a lot of trials going on
16 here.

17 MR. HARKINS: Sorry.

18 CHIEF JUDGE BUMB: What's your response? I think
19 he's right. What's your response?

20 MR. STANOCH: Your Honor, it simply goes to the
21 capabilities to perform the gas chromatography testing of ZHP's
22 valsartan API.

23 They argue we didn't have that testing, we didn't --
24 we had to hurry and scurry in July of 2018 to do it.

25 CHIEF JUDGE BUMB: And this shows that they did have

1 that testing available?

2 MR. STANOCH: Yes. Years prior they were doing
3 testing of valsartan API, albeit the one for another market, by
4 gas chromatography. And we'd like to show that they had --

5 CHIEF JUDGE BUMB: For that general proposition that
6 they did have that availability?

7 MR. STANOCH: Yes. Yes. They had the capability
8 in-house, right. And, in fact, they were doing it on valsartan
9 API they were making themselves for years. That's it.

10 CHIEF JUDGE BUMB: What do you say about that?

11 MR. HARKINS: Your Honor, there's a distinction that
12 keeps getting lost between having a machine that is capable of
13 performing gas chromatography and having that machine validated
14 with the appropriate settings in order to determine whether
15 nitrosamines are present in a product. There is no dispute
16 that Teva has --

17 CHIEF JUDGE BUMB: Okay. Try it again. Try that
18 again, please.

19 MR. HARKINS: There is no dispute that Teva has a gas
20 chromatography machine and that a gas chromatography machine is
21 available to the company generally.

22 CHIEF JUDGE BUMB: Okay.

23 MR. HARKINS: Trying to introduce evidence that at
24 some other location there was a gas chromatography machine
25 doesn't make the point that plaintiffs are attempting to make.

1 It is not as simple as taking the product and placing it in
2 that machine and that the testing can magically be performed.
3 That is what we are disputing.

4 CHIEF JUDGE BUMB: So you're saying that the gas
5 chromatography that was available at the time is not what is
6 necessary to detect nitrosamine in valsartan; it's a more
7 different procedure?

8 MR. HARKINS: It is the same machine, but it is using
9 a validated test method like the one that was only published by
10 the FDA in 2018, one that was -- such as the one that Teva
11 internally developed in 2018.

12 CHIEF JUDGE BUMB: Same machine, but different
13 instructions or something?

14 MR. HARKINS: Yes, Your Honor.

15 MS. DAVIDSON: Yes, Your Honor.

16 CHIEF JUDGE BUMB: Okay.

17 MR. STANOCH: This is a fact question. He says
18 they --

19 CHIEF JUDGE BUMB: Well, here's --

20 MR. STANOCH: Not to mention Mr. -- if I may.

21 CHIEF JUDGE BUMB: Yeah.

22 MR. STANOCH: Mr. Harkins says, oh, you need a
23 validated method. That's not what happened here, Judge.

24 CHIEF JUDGE BUMB: What evidence are you going to
25 introduce that -- what evidence does the plaintiff have that

1 having the chromatography machine, I'll call it, available
2 would have been sufficient?

3 MR. STANOCH: Because --

4 CHIEF JUDGE BUMB: Because that's what I understand
5 the argument to be made; that, yes, the machine was all
6 available, but what you throw into the machine and the
7 specifications and the knowledge that the machine had wasn't
8 available. What evidence do you have?

9 Because that would be confusing to the jury --

10 MR. STANOCH: Part --

11 CHIEF JUDGE BUMB: -- to argue that, well, they had
12 this and they could have easily run it, but it's a little bit
13 more complicated than that. So what evidence do you have?

14 MR. STANOCH: Well, the specification testing they're
15 using here, Judge, is testing of valsartan API for residual
16 solvents by gas chromatography. You're already testing
17 valsartan API. You're already doing a test with this machine.
18 This idea, which I'm hearing for the first time, that you
19 needed different instructions for the machine, they had this
20 machine instructed to do this test on valsartan API already.

21 MR. HARKINS: Your Honor, there is no need to open
22 the door to a sideshow where we need to explain what TAPI is,
23 what product they did or did not manufacture, and then why it
24 is irrelevant to the trial in order to get to the point that
25 Teva as a company has a gas chromatography machine. That is

1 not disputed.

2 If that's the point that plaintiffs are seeking to
3 introduce this for, the problem is they don't need it. This
4 opens the door to an entirely separate entity that is not at
5 issue in this trial.

6 CHIEF JUDGE BUMB: Okay. So you have a stipulation
7 from them that Teva had a gas chromatography machine. That's
8 what you want it for?

9 MR. STANOCH: Uh-huh. And that it was capable of
10 testing valsartan API, yes.

11 CHIEF JUDGE BUMB: I think therein lies the dispute;
12 no?

13 MR. STANOCH: I think so. And that's --

14 MR. HARKINS: Your Honor, we know that our experts
15 are going to make the point that I've just made; that using
16 that machine and simply sticking the API in it without
17 adjusting settings or knowing what to look for would not have
18 revealed nitrosamines. And I assume plaintiffs are going to
19 argue otherwise. That may be a question of fact for the jury,
20 but the introduction of TAPI to get to that point is
21 unnecessary.

22 CHIEF JUDGE BUMB: Fair enough.

23 So you have a stipulation from them that they had the
24 machine. Your experts are going to dispute about having the
25 machine, what that means, what that doesn't mean. You don't

1 need the TAPI report.

2 MR. STANOCH: Okay.

3 CHIEF JUDGE BUMB: Okay?

4 MR. STANOCH: Yes, Your Honor.

5 CHIEF JUDGE BUMB: Next one, just working through.

6 MR. HARKINS: And, Your Honor, I believe this is I,
7 related to Teva's commercial decision to stop selling
8 valsartan.

9 CHIEF JUDGE BUMB: Yeah. Uh-huh.

10 MR. HARKINS: Your Honor, we believe that there may
11 be a suggestion by plaintiffs that the decision Teva made
12 towards the end of 2018 to stop selling valsartan commercially,
13 to not reintroduce it to the market in the United States after
14 the recall was somehow evidence or an admission of wrongdoing.

15 There is conflicting testimony on this simply because
16 Teva was undertaking a commercial evaluation of the product
17 which coincided with the recalls. It is not to say that the
18 recalls didn't factor in some way into the decision not to
19 bring that product back to market. But this is all after the
20 recall. It has no bearing on any of the medication that was
21 purchased by the plaintiffs who are at issue in this TPP trial.
22 It, again, is just going to open the door to something that we
23 don't need to delve into because it's very difficult to
24 determine any relevance from Teva's late 2018 decision not to
25 return to the market, which didn't impact --

1 CHIEF JUDGE BUMB: Why wouldn't you want the jury to
2 hear that you stopped selling it after the recall? It somewhat
3 was perplexing to me.

4 MR. HARKINS: Your Honor, I don't think that what
5 we're opposing is the use of that simple fact that it was not
6 brought back to the market. That is not what we're saying. We
7 are opposing any suggestion -- we think plaintiffs should be
8 precluded from arguing that Teva knew there was this problem
9 with the product.

10 CHIEF JUDGE BUMB: Oh, because they stopped selling.

11 MR. HARKINS: And stopped selling it. There was
12 suggestion during some of the questioning at depositions that
13 perhaps the decision to stop selling it was evidence of
14 motivation by Teva, knowledge of some problem with the product
15 pre-recall. There is no evidence of that, and we think that
16 should not be unduly suggested.

17 CHIEF JUDGE BUMB: What are you trying to get at
18 here?

19 MR. STANOCH: This simply shows, Your Honor, that the
20 product was not salable. Teva stopped selling it, right. They
21 delisted it from the Orange Book in August 2018. Why did they
22 do that? Because it was recalled. It had NDMA, because it was
23 economically worthless, and there's no market for adulterated
24 drugs. That's what the issue is.

25 Their witnesses, 30(b)(6) witnesses say what all --

1 which, frankly, what I just said is sort of common sense.
2 There's a recall. A month later they stopped selling it.

3 CHIEF JUDGE BUMB: Yeah. I don't know why this is
4 even in dispute.

5 MR. STANOCH: Well, because their 30(b)(6) said, oh,
6 no, no, no, we did not stop selling it because of the recalls,
7 we did not stop selling it because of the NDMA, we had made a
8 commercial decision at some time --

9 CHIEF JUDGE BUMB: You're really going to make that
10 argument to the jury?

11 MR. HARKINS: No, Your Honor.

12 CHIEF JUDGE BUMB: Oh.

13 MR. HARKINS: The thing that we are opposing is the
14 separate statement that plaintiffs counsel just made; that
15 somehow the decision to do that is evidence of our admission
16 that the product is adulterated.

17 CHIEF JUDGE BUMB: Oh.

18 MR. HARKINS: Or our admission that the product is
19 worthless or not salable. All of that is going to be heavily
20 contested.

21 CHIEF JUDGE BUMB: You're going to argue to the jury
22 we stopped selling it because there was a recall, not that we
23 admitted it was adulterated?

24 MR. HARKINS: That's correct, Your Honor.

25 CHIEF JUDGE BUMB: Okay. Well, I guess it's a jury

1 question.

2 MR. STANOCH: I think so.

3 CHIEF JUDGE BUMB: It's a jury question.

4 MR. STANOCH: And, Judge, I don't think we're going
5 to really go far into this, frankly, unless they put their
6 witnesses up and say, oh, we made a commercial decision, we
7 stopped selling it, nothing to do with the recall.

8 CHIEF JUDGE BUMB: Yeah. Look, I think if that is
9 the door that is opened, then I think you would be permitted to
10 walk through it. But other than that, I just, I think it's --
11 it really goes to the defendants' defense, right?

12 MR. HARKINS: And, Your Honor, we think basic factual
13 information about when the product was taken off the market and
14 the fact that it was not brought back is obviously going to
15 come in.

16 CHIEF JUDGE BUMB: Yes.

17 MR. HARKINS: The problem we have is the allegation
18 that it might be evidence of an admission of wrongdoing or a
19 statement about the adulterated state of the product.

20 CHIEF JUDGE BUMB: I understand. I guess they're
21 permitted to rebut that. They're permitted to bring that
22 evidence in if that door somehow gets opened. But I don't --

23 MR. STANOCH: That's fair, Your Honor.

24 CHIEF JUDGE BUMB: Okay.

25 So what were you asking for me to exclude, the

1 argument?

2 I just think you're both saying the same thing.

3 MR. STANOCH: Well, perhaps you just take it under
4 advisement, Judge. It might not even --

5 CHIEF JUDGE BUMB: No, I'm not going to take anything
6 under advisement. I'm ruling. And my ruling is, if the door
7 is opened, it comes in. Okay?

8 MR. STANOCH: Yes. Thank you, Judge.

9 CHIEF JUDGE BUMB: All right. They're going to get
10 up and say we pulled it off the market because it was recalled
11 and, you know, not because we didn't think it was adulterated.
12 You're going to get up and say they pulled it off the market
13 because it was adulterated. Okay.

14 Okay. What's a "field alert"?

15 MS. LOCKARD: Your Honor, there is FDA requirement
16 that companies like Teva make a field notice or a field alert
17 report to FDA when there's a quality issue.

18 In this instance Teva did that, and at that point in
19 time FDA had already gotten the field alert from ZHP, was
20 already well aware of this nitrosamine issue, so it was not new
21 information.

22 In the depositions, there is a quibble or a quarrel
23 over whether that report was made timely and was it within the
24 three days. And when did Teva get notice that gave rise to a
25 reportable event? Was it when they first got notice that there

1 was an impurity? Was it when they found out it was a
2 nitrosamine impurity days later? And there's just a lot of
3 testimony about, well, was it within three days, was it not?

4 FDA never complained about the timing of the field
5 alert notice to Teva. There was never any issue with it. And
6 we're talking about a matter of days that we would be quibbling
7 over.

8 In order to put this before the jury, we would have
9 to go through all of the timeline of when did we find out,
10 interpret the FDA regulations about when you're supposed to
11 make a field alert. And ultimately, it doesn't matter because
12 it's all after Teva stopped the product. They put a hold on
13 their product. So none of the plaintiffs in this case got any
14 of that product after Teva learned from ZHP that there was an
15 issue.

16 CHIEF JUDGE BUMB: Why is it probative?

17 MR. STANOCH: Your Honor, we just heard a lot about
18 the timeline of what Teva knew, when, and what it was supposed
19 to do under FDA regulations about reporting an incident with
20 their product. Those are all fact questions the jury is going
21 to hear anyway.

22 I'll also add before I go more specifically, Your
23 Honor, that Judge Kugler already allowed and denied Teva's
24 motion to preclude, under 702, our cGMP expert's opinions,
25 which are very discrete. This is not a tail-wagging-the-dog

1 situation. Very discrete set about this issuance of timing.

2 You're required to report under FDA regulations
3 within a certain time. We have facts, we think from their
4 witnesses and admissions, that say they didn't. And they
5 dispute that. And a jury is going to hear that. It goes to --

6 CHIEF JUDGE BUMB: What does it go to?

7 MR. STANOCH: It goes to Teva's compliance with cGMP
8 and FDA regulations, right? It's a violation of the
9 regulations and their obligations as a manufacturer.

10 It also goes to their motive and state of mind and
11 potentially punitive damages as well. They're slow playing,
12 our argument, based on the facts we have, slow playing the
13 announcement to the FDA about this issue when they should have
14 taken action, by their own SOPs and FDA regs, much, much
15 sooner.

16 CHIEF JUDGE BUMB: What's the evidence why there was
17 a delay? What will the evidence be?

18 MS. LOCKARD: Well, the evidence is that Teva first
19 learned of a previously unknown impurity that may have a
20 genotoxic potential on June 20th. On June 21st, Teva issued an
21 immediate halt. No plaintiff got product after that.

22 On June 25th, ZHP notified Teva that the impurity was
23 possibly or probably NDMA.

24 On June 28th, after Teva's quality department had
25 investigated this, spoken with ZHP, they determined they had a

1 reportable event. It was then the weekend, the holiday
2 weekend, and ultimately they reported to FDA on July 3rd. So
3 even taking plaintiffs' best-case scenario, we're talking about
4 from June 20th to July 3rd. And in the meantime, all the
5 product was on hold.

6 This case, remember, is about the TPPs and whether
7 they bought worthless product. What FDA was doing and
8 requiring in terms of field reporting, asking the jury to then
9 come in and stand in the shoes of the FDA and say, well, did
10 Teva, did they meet this obligation to report in three days or
11 did they not, it doesn't matter because it's not probative of
12 whether the plaintiffs got a worthless drug.

13 CHIEF JUDGE BUMB: The product was on hold, right?

14 MR. STANOCH: Your Honor --

15 CHIEF JUDGE BUMB: Do you disagree with that?

16 MR. STANOCH: A hold is not a recall. A hold is not
17 a recall. There's product in the market.

18 CHIEF JUDGE BUMB: But it -- yeah.

19 MR. STANOCH: That was available and used and
20 purchased already. The recall is what triggers everyone to
21 say, stop, don't do anything. Return it. Throw it away.

22 CHIEF JUDGE BUMB: What's a hold do? You can't sell
23 it.

24 MR. STANOCH: That was a hold internally at Teva
25 saying we are not going to sell it to our distributors anymore.

1 None of that went outside the doors of Teva, which is part of
2 our point, Judge.

3 A hold is Teva commercial: Just say don't sell it if
4 Mckesson or AmerisourceBergen comes to you and says we need
5 more valsartan. Don't sell them any more.

6 CHIEF JUDGE BUMB: But it didn't tell the payors to
7 stop selling.

8 MR. STANOCH: Didn't tell anyone. Didn't tell
9 payors, consumers, pharmacies, the FDA. They were still
10 probably being sold and used between June 20th and the recall
11 on July 16th.

12 CHIEF JUDGE BUMB: Okay. Do you agree with that;
13 that the hold did not tell those outside the walls of Teva
14 don't sell? Do you agree with that statement?

15 MS. LOCKARD: I agree with that in its purest form.
16 And by that I mean, they can question our witnesses and say,
17 you never told any of your distributors about this until X
18 date, did you? Or you never told anyone outside of Teva about
19 this until X date. That's fine.

20 But to get into the FDA regulations and say, well,
21 FDA requires that you report in this amount of time, and to try
22 to impose and put the jury in the shoes of the FDA, I mean,
23 we're getting into *Buckman* territory there. They should not be
24 doing that.

25 The timeline when we notified our distributors and

1 the outside world, that's fair game, I agree. But that's
2 different.

3 MR. STANOCH: Your Honor, they had three days. It
4 took them a month.

5 CHIEF JUDGE BUMB: Okay. Here's my ruling: I think
6 that I do agree with Ms. Lockard that I think that it does get
7 a little far afield to get into what the FDA required. The
8 timeline is clearly relevant to this case. It's clearly
9 relevant. I will reserve the issue of reporting to the FDA
10 what the plaintiffs say is beyond the time. It might be
11 relevant at the punitive stage, okay?

12 MR. STANOCH: Thank you, Judge.

13 CHIEF JUDGE BUMB: Okay. Next.

14 MR. HARKINS: Your Honor, the next motion relates to
15 evidence of Teva's sales that were outside the United States
16 post recall. This is not something that was subject to
17 discovery. We feel that it's clearly irrelevant to the case.
18 It also would require us educating the jury on foreign
19 regulatory requirements, because it is simply true that not
20 every country imposed the same restrictions on salable product
21 with respect to nitrosamines at the same time that the United
22 States did.

23 There are some stray references that were brought up
24 with one of our witnesses that talk about Teva's efforts and
25 discussions about potential non-U.S. post-recall sales.

1 They have no bearing on this trial which relates to
2 product that was sold in the United States before the recall to
3 the plaintiffs at issue.

4 CHIEF JUDGE BUMB: Okay. That evidence is out unless
5 the door is opened.

6 MR. STANOCH: Fair.

7 CHIEF JUDGE BUMB: Okay. Is that it for Teva's?

8 MS. LOCKARD: There's one final motion, Your Honor.

9 CHIEF JUDGE BUMB: Oh.

10 MS. LOCKARD: This one relates to the potential
11 references related to alleged destruction of the product or API
12 after the recall.

13 Now, there are, I would say, bits of testimony that
14 that have come out. One, for example, I can tell you is that
15 someone at Teva had a conversation with someone at FDA about,
16 early after the recall, about allowing the destruction of the
17 product and does FDA agree that it can be destroyed based on
18 the FDA's...

19 (Court reporter clarification.)

20 CHIEF JUDGE BUMB: That it can be destroyed based on
21 what?

22 MS. LOCKARD: Based on the FDA's processes for
23 conducting the recall. Because remember at this time, FDA is
24 also working with Teva over its recall process. What are we
25 going to do with all this product that has been recalled? And

1 does Teva need to store all of it? Or at least under the FDA's
2 guidance, is it allowable to destroy that? So that's one
3 discussion. You've got to check the box with the FDA. They
4 have to approve. FDA said yes, you can destroy this.

5 In this case, we absolutely complied with all of the
6 hold notifications and requirements for preserving evidence.
7 The plaintiffs tried to make a run at this earlier in
8 discovery, and the Honorable Judge Vanaskie said, no, we're not
9 going to go down this. There's no evidence of spoliation. We
10 provided notice to plaintiffs that we would be preserving a
11 reasonable amount, which Judge Vanaskie instructed us to do.
12 We preserved that. So there is no spoliation in this case as
13 to Teva.

14 There are also references to what was happening in
15 other countries, for example, in Japan where Teva does business
16 and distributes valsartan under a different API manufacturer
17 and whether they were destroying that over there. All of that
18 is totally irrelevant to the drugs that were sold and that are
19 at issue in this case.

20 And so there's just this ether of destruction, did
21 you destroy? It permeates. They asked all the witnesses about
22 it trying to tie together some argument that there was this
23 spoliation issue. And --

24 CHIEF JUDGE BUMB: What do you want to do with this,
25 Mr. Stanoch?

1 MR. STANOCH: We're not trying to prove spoliation,
2 Your Honor.

3 CHIEF JUDGE BUMB: What are you trying to do?

4 MR. STANOCH: We're trying to do two things. One, it
5 certainly goes to the economic worthlessness of the drug. Teva
6 was -- this wasn't following FDA procedures. They were
7 constantly badgering the FDA, oh, can we destroy it, can we
8 destroy it, can we destroy it, can we destroy it?

9 It goes to both -- it's worthless. They couldn't
10 sell it so they had to destroy it, we think, for damages.
11 Number two, it goes to motive and egregiousness in punitive
12 damages. We're not trying to prove --

13 CHIEF JUDGE BUMB: What? That they got rid of the
14 drug that was recalled? I don't understand. How does that go
15 to punitives?

16 MR. STANOCH: Yes. That this wasn't a routine
17 destruction. Their testimony admitted that they did destroy a
18 product, notwithstanding a litigation hold, and that it wasn't
19 just simply FDA --

20 CHIEF JUDGE BUMB: What did you want -- I'm sorry.
21 I'm losing you. You wanted them to store all of these --
22 this -- you wanted them to store this all pending the
23 litigation, all of their lots?

24 MR. STANOCH: No, Your Honor.

25 CHIEF JUDGE BUMB: What did you want them to do?

1 MR. STANOCH: The contemporaneous documents showing
2 the eagerness with which they were trying to destroy this
3 product shows that they're trying to get rid of it.

4 CHIEF JUDGE BUMB: Keep their house in order.

5 MR. STANOCH: That's a question for the jury.

6 CHIEF JUDGE BUMB: No. That's -- I think that's
7 unfair. I think that's just speculative.

8 MR. STANOCH: We have testimony.

9 CHIEF JUDGE BUMB: What's the testimony?

10 MR. STANOCH: That they did, in fact, destroy product
11 that was admittedly subject to a litigation hold, and they did
12 not tell their domestic recall vendor about the litigation
13 hold.

14 CHIEF JUDGE BUMB: But Judge Vanaskie didn't find any
15 evidence of spoliation. What, did you want them to just store,
16 you know, bins full of medicine pending this litigation? Is
17 that what you're saying?

18 MR. STANOCH: No. And we're not asking for a
19 spoliation reference.

20 CHIEF JUDGE BUMB: What are you -- tell me what
21 relevance this evidence has.

22 MR. STANOCH: They had to destroy it because it was
23 worthless.

24 CHIEF JUDGE BUMB: They had to destroy it because it
25 was worthless?

1 MR. STANOCH: They couldn't do a thing with it.

2 MS. LOCKARD: Well, we couldn't sell it at that point
3 once it's recalled.

4 CHIEF JUDGE BUMB: Yeah. I don't think it's -- I
5 think it adds -- I don't even think it adds value to the case.
6 I mean, I don't know one juror who wouldn't think that once
7 it's recalled it should be destroyed.

8 MR. STANOCH: They were selling it in other markets.
9 But that is the last motion. But I understand your ruling,
10 Judge.

11 CHIEF JUDGE BUMB: Okay. What's the last motion,
12 then? Okay.

13 MR. STANOCH: I think that's it. I think that's it
14 for this motion.

15 CHIEF JUDGE BUMB: Oh. I thought you said they had
16 one more motion. Is that it for Teva?

17 MR. HARKINS: Yes, Your Honor.

18 CHIEF JUDGE BUMB: Okay. So what I'm going to ask to
19 do, so at the end of our proceedings, if this was your motion,
20 then I'm going to ask you to draft an order for my approval
21 that will set forth what my rulings are, okay?

22 2646 is my next motion. ZHP's motions in limine.

23 MS. DAVIDSON: Your Honor, in the spirit of giving
24 our associates court experience, we've asked some of them to
25 handle some motions today.

1 CHIEF JUDGE BUMB: Please.

2 MS. DAVIDSON: I'm sure Alex will do a great job, but
3 I do want Your Honor and everyone to know, it's his first oral
4 argument. Thank you.

5 CHIEF JUDGE BUMB: Fantastic. Come forward, please.

6 MR. KASPARIE: Thanks, Your Honor. Alex Kasparie.

7 CHIEF JUDGE BUMB: You're welcome to use the podium.

8 MR. KASPARIE: All right. Thank you, Your Honor.

9 THE COURT REPORTER: Can you spell your name for the
10 record.

11 MR. KASPARIE: Sure. K, as in kite, A-S-P, as in
12 Paul, A-R-I-E, Alexander.

13 CHIEF JUDGE BUMB: Should we just let him win?

14 (Laughter.)

15 MR. KASPARIE: I think Adam might have something to
16 say about that.

17 MR. SLATER: Based on his opponent on this, he
18 probably will.

19 (Laughter.)

20 MR. KASPARIE: Good morning, Your Honor.

21 CHIEF JUDGE BUMB: Good morning.

22 MR. KASPARIE: I will keep this short and sweet. On
23 the first motion in limine, we're seeking to -- we're seeking
24 to omit two irrelevant documents from Remonda Gergis. One of
25 them is from 2010. The other is from 2015. On the first memo

1 there's nothing that ties that memo to either one of the
2 facilities that produced valsartan or even that it was a
3 valsartan-related process. It also relates to what I'll call
4 commercial hygiene issues that are just not at issue in this
5 case.

6 The second is an email chain that does involve
7 valsartan. Certain products were misstamped, the little stamps
8 on top of each pill that you get, certain valsartan pills were
9 misstamped. Ms. Gergis thought that that was caught too late,
10 and there's email traffic about that.

11 Neither of those documents are probative of the
12 issues at issue in this case. And both of them are extremely
13 prejudicial and can only be used to show propensity or some
14 other form of --

15 CHIEF JUDGE BUMB: Because the missed -- the fact
16 that it was misstamped is not really relevant to the issue
17 here.

18 MR. KASPARIE: No, Your Honor. No, no. The stamping
19 has nothing to do with anything at issue in this case.

20 CHIEF JUDGE BUMB: Yeah. Okay. So the first email
21 is, tell me again.

22 MR. KASPARIE: The first is a memorandum from 2010.
23 It involves what I'll call "industrial hygiene issues."

24 CHIEF JUDGE BUMB: Yes.

25 MR. KASPARIE: The way certain hoses were labeled.

1 CHIEF JUDGE BUMB: Yes.

2 MR. KASPARIE: We don't actually know for certain
3 what facility this relates to. So it would just be speculation
4 that it relates to the valsartan facility. And the other
5 matter is it's in 2010, three years before the earliest process
6 is put in place.

7 CHIEF JUDGE BUMB: Right. So the 2010 email is out.
8 I agree with you.

9 Let me hear on the second email. That was 20 --

10 MR. KASPARIE: 15, Your Honor.

11 CHIEF JUDGE BUMB: 2015. Yeah. I was going to say
12 '16.

13 Who's arguing?

14 MR. SLATER: I am, Your Honor.

15 CHIEF JUDGE BUMB: Yeah. Mr. Slater.

16 MR. SLATER: Your Honor, the bottom line on that is
17 that Ms. Gergis, who was a quality professional at Princeton,
18 Princeton was the customer from ZHP. They're the -- their
19 own -- ZHP owns Princeton essentially. But her observation was
20 that ZHP's quality practices were substandard. Princeton was
21 purchasing. They had a quality agreement in place. And the
22 entire purpose of this is to show that Princeton was aware that
23 there were quality issues, which is a corporate cultural issue
24 in terms of how a company operates its entire processes.

25 CHIEF JUDGE BUMB: But you agree it was with respect

1 to the stamping, right?

2 MR. SLATER: Yes. It was with regard to the
3 stamping. So the only relevance would be that Princeton was
4 aware there were quality issues, and that would be the
5 relevance of it.

6 CHIEF JUDGE BUMB: Well, Princeton was aware that
7 there was a quality issue with respect to the stamping. See,
8 that's the issue. And I guess as the gatekeeper of the
9 evidence that goes before the jury, under 401 and 403, to take
10 a statement that's very, very broad, and you have to keep it
11 all in context.

12 So if the issue of stamping becomes even relevant, I
13 don't know how it becomes even relevant in this case, then,
14 yes, this email comes in, but I don't see the relevance of it.

15 MR. SLATER: I don't have a strong argument to
16 provide to the Court beyond what I've said.

17 CHIEF JUDGE BUMB: You have just prevailed on both of
18 your arguments.

19 MR. KASPARIE: Thank you, Your Honor.

20 (Laughter.)

21 MR. KASPARIE: I've got the second motion as well if
22 you'd like to go into that.

23 CHIEF JUDGE BUMB: Yes.

24 MR. KASPARIE: So the second motion -- and I want to
25 be clear on what the second motion is. The second motion is

1 only about the destruction of batches C5191-17-023 and 024. We
2 are not seeking to prohibit plaintiffs from discussing the
3 identification of an out-of-specification substance that are in
4 those batches.

5 The only thing we're trying to preclude is some sort
6 of spoliation inference or suggestion that we destroyed these
7 batches somehow to hide something.

8 CHIEF JUDGE BUMB: And they're not going to make that
9 argument, are you, Mr. Slater?

10 MR. SLATER: No. The argument's not going to be that
11 they were destroyed to hide something. The argument would be,
12 as recognized in the establishment inspection report from the
13 FDA, that the company did not properly address an
14 out-of-specification issue which shows that ZHP -- and this is
15 something that is an issue that permeates, and again, it's in
16 the EIR -- was permeating their lack of quality practices
17 across the board. And it relates directly to what we're
18 talking about in the case, because that's the problem with ZHP,
19 is that their quality practices were so substandard and
20 careless.

21 So the FDA actually criticized what happened here and
22 said you needed to do a full investigation, you didn't -- these
23 samples were destroyed, they shouldn't have been. They should
24 have been tested, which they were not. So that's the point.
25 Not to say that it was a hiding issue. It's a lack of quality

1 care, which is obviously the cGMP issue.

2 CHIEF JUDGE BUMB: So do you agree that it comes in
3 for that limited purpose and then that becomes a relevance --
4 it becomes a weight of the evidence, it becomes a jury
5 question? It does not come in and should not come in to
6 somehow suggest to the jury or, you know, through, you know,
7 intimate to the jury that it was a spoliation.

8 MR. KASPARIE: I think if it comes in only, and only
9 for the notion that somehow the destruction wasn't how an
10 investigation should typically proceed, that's fine. I just
11 don't want to get into the destruction -- I don't want it all
12 to be about the destruction because then I think we have to go
13 into, well, then was there a duty to preserve the evidence and
14 that kind of argument.

15 CHIEF JUDGE BUMB: I think it comes in for the
16 limited purpose that Mr. Slater said, and that's it, okay?

17 MR. KASPARIE: Thank you.

18 CHIEF JUDGE BUMB: And if it delves into spoliation
19 and somehow it delves into something much broader, then I'll
20 issue a limiting instruction for the jury, okay?

21 MR. KASPARIE: Thank you.

22 CHIEF JUDGE BUMB: Is that it for 2646?

23 MS. ROSE: There's one more motion, Your Honor.

24 CHIEF JUDGE BUMB: Okay.

25 MS. ROSE: Mr. Kasparie was doing so well, I should

1 have just let him continue.

2 This motion is about a hearsay email or a set of
3 hearsay emails between two non-ZHP employees following the
4 discovery of NDMA.

5 Very brief background, I know you have the motion, is
6 that Min Li who worked at ZHP reached out informally to a
7 friend of his following the discovery of NDMA seeking advice.
8 They had a discussion. We are not seeking to exclude that
9 discussion because Min Li is a party opponent.

10 Subsequent to that, Mr. Wang, not a ZHP employee,
11 took it upon himself to reach out to another friend and say:
12 My friend at a different company is having this issue with
13 NDMA, would you be interested in potentially consulting?

14 That was to James MacDonald. Mr. MacDonald said, no,
15 didn't have time.

16 Plaintiffs are now seeking to introduce those emails
17 between Mr. Wang and Mr. MacDonald, hearsay emails about NDMA
18 and the potential risks of NDMA as evidence, but it's classic
19 hearsay that they want to enter for the truth of the matter
20 asserted.

21 CHIEF JUDGE BUMB: Okay. What is exactly the email?

22 MS. ROSE: Sure. It is a string of emails.

23 CHIEF JUDGE BUMB: What page is it on your motion
24 here? I have it here.

25 MS. ROSE: It would be Exhibit 7 to the Davidson

1 certification.

2 CHIEF JUDGE BUMB: Okay. I don't have that up here.

3 But --

4 MR. SLATER: If it's helpful, our brief, I think, had
5 a decent historical run-through of the emails.

6 CHIEF JUDGE BUMB: I think so, yeah. I think so. If
7 I have them here.

8 Who will be -- let me ask your adversary, who will be
9 testifying to these emails?

10 MR. SLATER: Min Li, who I deposed as a corporate
11 30(b)(6) representative of ZHP.

12 CHIEF JUDGE BUMB: So --

13 MR. SLATER: And if depending on how the argument
14 goes, we have Jim MacDonald under subpoena.

15 CHIEF JUDGE BUMB: So how's it go? Li's on the
16 stand, how's it go?

17 MR. SLATER: The testimony obviously has already been
18 taken. The story that comes through the testimony is this:
19 The problem comes out, and Min Li, who's the head of the
20 analytical labs at ZHP, reaches out to Charles Wang, who's
21 working for Glaxo actually, so he's moonlighting now for ZHP.
22 And he hires him and they paid him to consult on this issue,
23 because ZHP said, what do we do now?

24 Because their goal was, and the documents show it and
25 the testimony shows it, was to keep as much of this product on

1 the market as possible. So what they wanted to make is the
2 strongest argument they could make to the FDA to push up the
3 allowable threshold. Because the FDA was now going to say --
4 decide whether any of this could be on the market so they
5 needed people to support that.

6 So Charles Wang looks at it and he says, okay, I'm
7 looking at this, this is what I think.

8 CHIEF JUDGE BUMB: To Li?

9 MR. SLATER: To Li, yes. The conversation is between
10 the two of them.

11 CHIEF JUDGE BUMB: And then Wang reaches out to
12 MacDonald, "hey."

13 MR. SLATER: Because he first goes to Min Li and
14 says, hey, I think we need someone super specialized not only
15 in the regulatory issues but also with regard to the
16 carcinogenicity of such toxic products, and he's told yes, go
17 ahead and do that. So they're all acting as agents on behalf
18 of the company.

19 CHIEF JUDGE BUMB: When Wang reaches out to
20 MacDonald, is Li on the email?

21 MR. SLATER: He's not on a direct communication, as
22 we obviously addressed in the brief, that I think the agency
23 principle encompasses, as well as the state-of-mind issues.

24 CHIEF JUDGE BUMB: I know.

25 MR. SLATER: Because what he does is he goes to Jim

1 MacDonald and says, hey, we have got this problem, here's
2 what's going on. Jim MacDonald says, I'm on vacation. Min Li
3 sends him the information, tells him what's going on. And Jim
4 MacDonald gives a very detailed analysis for why -- and I'm
5 paraphrasing but summarizing -- his ultimate conclusion was he
6 said it's such high levels that he thought it was 30 parts per
7 million. It turns out the levels were actually much higher.
8 Your company is going to have a very difficult time keeping
9 this on the market. I think they need to make other
10 arrangements.

11 CHIEF JUDGE BUMB: That email goes to who?

12 MR. SLATER: That email goes back to Charles Wang.
13 Charles Wang then tells Min Li, and Min Li acknowledged that
14 and it's in the testimony, that this information was then
15 provided to Min Li and they then worked through this.

16 Min Li --

17 CHIEF JUDGE BUMB: The email or the information?

18 MR. SLATER: The information. Charles Wang
19 communicated what Jim MacDonald had said to Min Li. And that's
20 what he testified. That's what Min Li testified to.

21 CHIEF JUDGE BUMB: And so what was communicated to
22 Min Li comes in. And if there's a dispute about how it was
23 communicated and how he learned, then the email may come in.
24 But you don't need the email now. Because he never saw the
25 email. He never adopted the email.

1 MR. SLATER: Right.

2 CHIEF JUDGE BUMB: He never instructed Wang to go,
3 you know, reach out. There's an agency argument. I think it's
4 a little too -- unless you're going to say -- unless the --
5 here's my ruling: If the testimony is that Li instructed Wang
6 for Wang to reach out to MacDonald --

7 MR. SLATER: Which it is. MacDonald -- Wang asked
8 MacDonald -- Wang said to Li, can I do this? Can I go to this
9 other person? And Min Li said, yes, you can do it. And then
10 he went out and contacted Jim MacDonald with ZHP's knowledge
11 and clearances.

12 CHIEF JUDGE BUMB: Okay.

13 MS. ROSE: Your Honor, may I be heard just on that
14 point?

15 CHIEF JUDGE BUMB: Is that wrong?

16 MS. ROSE: For a point of clarification.

17 CHIEF JUDGE BUMB: Yeah.

18 MS. ROSE: So several things that Mr. Slater said, I
19 just wanted to clarify.

20 CHIEF JUDGE BUMB: Yeah.

21 MS. ROSE: One, he said that Charles Wang was being
22 paid by ZHP to provide this consulting service. At that
23 point -- at this point that this email happened, that was not
24 the case. Min Li reached out in a friendly capacity. Charles
25 Wang's email to Jim MacDonald says: My friend is having this

1 issue, what do you suggest? It was very informal.

2 CHIEF JUDGE BUMB: Okay. So there was no -- there
3 was no contract or retainer.

4 MR. SLATER: He was paid. Charles Wang was paid.

5 CHIEF JUDGE BUMB: Well, at that time of the email is
6 what she's trying to clarify.

7 MS. ROSE: At the time of the email. Subsequently
8 Charles Wang provided a report on NDMA for which he was paid on
9 a contract basis. But the email that Min Li sent to Charles
10 Wang was in an informal capacity right after the discovery of
11 NDMA.

12 MR. SLATER: This is --

13 CHIEF JUDGE BUMB: Okay. Li's testimony, Li's
14 testimony will be that he learned that MacDonald said the
15 levels are so much higher, you're in trouble. Is that the
16 testimony that you're eliciting?

17 MR. SLATER: Yes, in summary. And it's in our brief,
18 that I asked him, I asked Min Li --

19 CHIEF JUDGE BUMB: What page?

20 MR. SLATER: It's on page 9 of our brief, Your Honor,
21 in opposition to the ZHP motions.

22 CHIEF JUDGE BUMB: Okay. "Mr. Wang relayed to you
23 that he had spoken with Jim MacDonald and what the result of
24 that interaction had been."

25 He said, "I don't remember the details. He probably

1 talked to me verbally, at least. He also confirmed that this
2 information was provided to Jun Du, at a certain point, you
3 know, he came to know."

4 So he never saw the email, presumably. He was -- he
5 had a conversation with MacDonald, presumably. He doesn't
6 remember the details. You'll have to tie it up that what
7 MacDonald reported to Wang in an email was somehow provided to
8 Li.

9 MR. SLATER: And --

10 CHIEF JUDGE BUMB: Either through conversations,
11 because there's no email chain.

12 MR. SLATER: I just -- I wanted to clarify one thing
13 for the record.

14 CHIEF JUDGE BUMB: Yeah.

15 MR. SLATER: Your Honor said MacDonald's email. You
16 meant Wang. I just wanted to make that clear. The emails
17 were -- or the communications I think you said MacDonald. You
18 meant Wang possibly. But the point is, I asked Min Li that
19 exact question.

20 CHIEF JUDGE BUMB: Yeah.

21 MR. SLATER: And he said, as you just read, that this
22 information was provided to him and then he passed it on to Jun
23 Du.

24 Just so Your Honor knows who Jun Du is, he's the
25 chief executive of all of the United States entities owned by

1 ZHP and the vice-chairman of the board of ZHP.

2 So -- and he was working -- he's -- Min Li was
3 reporting to Jun Du and to Baohua Chen and to others in the
4 company. So giving this information to Jun Du was critical
5 because Jun Du was the highest decision-maker for all the
6 U.S. entities.

7 CHIEF JUDGE BUMB: And Li passed that on to Du.

8 MR. SLATER: Min Li said --

9 CHIEF JUDGE BUMB: Passed that on to Du.

10 MR. SLATER: Right. So this information was now
11 corporate information that they were acting on. And I don't
12 agree with -- oh, sorry.

13 CHIEF JUDGE BUMB: Right. I understand all of that.

14 So the evidence comes in. The question is, does the
15 email itself come in? And unless you can tie it in that
16 somehow that that email was either adopted by Li, that Li saw
17 it, it doesn't come in, because it's the information contained
18 within the email that Li was made aware of but not the email
19 itself.

20 MR. SLATER: I understand. So the testimony about
21 what it said and what was communicated is acceptable, but the
22 document itself, you're ruling at this point, based on the
23 record, would not actually go into evidence.

24 CHIEF JUDGE BUMB: Yeah. Because I don't think you
25 have a proper foundation.

1 MS. ROSE: Your Honor --

2 MR. SLATER: And if something comes up, again, I told
3 the Court, we have Mr. MacDonald under subpoena in case he
4 needs to come, in case the issue becomes important.

5 CHIEF JUDGE BUMB: Yeah. I mean, if he says, you
6 know, I sent the email to him, I read it to him. I don't know
7 what he's going to say, but then it's a different issue, yes.

8 MR. SLATER: Understood. We're satisfied with the
9 information coming in anyway, obviously. That's most important
10 for us. So we're good with that.

11 MS. ROSE: Your Honor, just two quick points. One
12 point of clarification, so Min Li's testimony is preserved
13 through deposition, so he won't be appearing at trial.

14 So the testimony that Mr. Slater is trying to admit
15 is Mr. Slater reading Jim MacDonald's email to Min Li and
16 asking him about it.

17 CHIEF JUDGE BUMB: And does he say, "No, I never saw
18 that"?

19 MS. ROSE: He just -- he never said he saw the email.
20 This is -- the only point he made is --

21 CHIEF JUDGE BUMB: What does he say to it?

22 MS. ROSE: "I don't remember the details." He
23 probably -- this is -- he's talking about Charles Wang. "He
24 probably talked to me verbally, at least." So --

25 CHIEF JUDGE BUMB: The email itself doesn't come in.

1 MS. ROSE: Okay.

2 CHIEF JUDGE BUMB: Okay.

3 MS. ROSE: And so the portion of the deposition
4 testimony at issue is Mr. Slater reading the email to Min Li
5 and asking him, are you aware of this, like asking him about
6 the email. So I think -- I just want to be clear that that
7 testimony would not come in.

8 CHIEF JUDGE BUMB: Well, then you'll have to sanitize
9 the deposition somehow. The parties will have to agree that
10 the question before was, were you aware of a certain document.
11 I don't know. You're not going to be able to read the email.
12 Because if the email doesn't come in, you can't ask the jury to
13 read the email and he says I never saw it before.

14 MR. SLATER: Well, I think that the email also comes
15 in under the state of mind exception to the hearsay rule,
16 because this was information that -- the next sentence in our
17 brief we pointed out that Charles Wang told Jim MacDonald, I
18 agree with your call and will pass the message to Huahai, which
19 is ZHP. And it was acknowledged by Min Li that information was
20 passed, and then Min Li said I then passed it on to Jun Du.
21 These are two of the top executives in the entire company.

22 CHIEF JUDGE BUMB: The information, not the email.
23 We have to be careful what we're talking about.

24 MR. SLATER: The information in the email was passed
25 along to the company and the company then relied on that and

1 had that information and took it into account in making its --
2 in taking its position as to toxicity and whether or not they
3 could keep the product on the market at what level.

4 CHIEF JUDGE BUMB: Right. But her argument is, is
5 that the email itself shouldn't come in. Therefore, you
6 shouldn't be allowed to read the email to Li to come in, and I
7 agree with that. But the information that was contained
8 therein, what the subject matter was, comes in. So you folks
9 will have to figure out a way how to play that testimony.
10 You're going to have to sanitize it somehow.

11 MR. SLATER: Okay.

12 MS. ROSE: And, Your Honor, one point that Mr. Slater
13 just raised about Jim MacDonald, him potentially being called
14 as a witness, that's another issue that's in dispute. We don't
15 have to address that now, but I'm offering to if you would like
16 to.

17 CHIEF JUDGE BUMB: Okay. Let's address it. The more
18 I can rule on, the better.

19 What will MacDonald add to the case?

20 MS. ROSE: Oh, sorry, I'll let you go first, Adam.

21 CHIEF JUDGE BUMB: Mr. Slater.

22 MR. SLATER: I actually -- we subpoenaed him in case.
23 In case of a ruling that would hinge on whether or not he could
24 come to court to testify to his discussions with Charles Wang,
25 to what he told him, to what the email was he wrote, in case

1 that was going to solve a hearsay issue if the Court felt like
2 that would solve it. I didn't know where the arguments would
3 go. So I had him ready. I have him ready under subpoena.

4 CHIEF JUDGE BUMB: The point of all of the testimony
5 and the relevance is, is that the plaintiffs want to introduce
6 testimony that Li was made aware of what MacDonald's views
7 were, right?

8 MR. SLATER: Which he testified he was.

9 CHIEF JUDGE BUMB: Which he testified to. So all of
10 this, you know, bringing MacDonald in and bringing the email
11 in, which you can't impute the email itself to Li, seems to be
12 just a little bit -- we're getting a little carried away.

13 MR. SLATER: If it's not testimony, it's fine. We
14 only did it in case.

15 CHIEF JUDGE BUMB: Okay. So they're not calling
16 MacDonald.

17 MR. SLATER: Our interest was the information,
18 because the information was within ZHP's knowledge. They had
19 it. They used it in their corporate decision-making.

20 CHIEF JUDGE BUMB: Understood.

21 So they're not calling MacDonald.

22 MS. ROSE: Thank you, Your Honor.

23 CHIEF JUDGE BUMB: Okay.

24 MR. SLATER: Thank you, Your Honor.

25 CHIEF JUDGE BUMB: Okay.

1 MR. SLATER: I think those are the three motions.

2 CHIEF JUDGE BUMB: Okay. Should we take a -- is it
3 really 11:30? Let's take a five-minute break, okay.
4 Ten-minute break, okay.

5 THE COURTROOM DEPUTY: All rise.

6 (Recess was taken at 11:30 a.m. until 11:46 a.m.)

7 THE COURTROOM DEPUTY: All rise.

8 CHIEF JUDGE BUMB: Okay. Moving right along. 2647.
9 Oh, these are the improper designations.

10 Yeah. Let's talk about this. This gets a little
11 complicated, doesn't it?

12 Okay. Who wants to talk to me about these? There
13 should be some that are live, via video, and some who are not.
14 And here's what I'll say, is that if they're available to come
15 in live, they'll come in live.

16 Maybe they'll testify by video. But my general rule
17 is the least amount of readbacks as possible go to the jury.
18 So with those parameters, what do you want to say?

19 MR. SLATER: This is -- Your Honor, in terms of -- I
20 think this is the motion on what we titled "improper deposition
21 designations."

22 CHIEF JUDGE BUMB: Which one?

23 MR. SLATER: I'm assuming that, or are we just
24 talking general about the trial?

25 CHIEF JUDGE BUMB: This is just general for now,

1 yeah.

2 MR. SLATER: Oh, I'm sorry.

3 From the plaintiffs' perspective, there's a lot of
4 witnesses that they're -- they're in China.

5 CHIEF JUDGE BUMB: Yeah.

6 MR. SLATER: They're in foreign countries. And
7 they're corporate representatives, so we have the testimony,
8 and our plan is to play those videos for those witnesses.

9 CHIEF JUDGE BUMB: Videos, yes.

10 MR. SLATER: There's -- I don't expect a lot of
11 corporate witnesses affirmatively put on in the plaintiff case
12 for that reason, because we just -- we don't have access to a
13 lot of these people.

14 Obviously experts we plan to bring in. I suppose if
15 an issue pops up, we would have to talk to the defense and
16 approach the Court.

17 CHIEF JUDGE BUMB: Experts are live.

18 MR. SLATER: We plan, yes.

19 CHIEF JUDGE BUMB: Yes.

20 MR. SLATER: Yes.

21 CHIEF JUDGE BUMB: Okay. Experts are live.

22 MS. LOCKARD: Yes.

23 CHIEF JUDGE BUMB: Yes.

24 MR. SLATER: I know that we'll at some point want to
25 start to talk to the Court about preserving testimony for

1 experts where we have so many cases that may get sent out where
2 it would be impossible for our experts to be at all the trials.

3 CHIEF JUDGE BUMB: No, let's just focus on
4 November's.

5 MR. SLATER: Right. I just wanted to say that for
6 the future. But that's our plan. We have -- we have plaintiff
7 witnesses affirmatively who will be on the stand for the TPPs.

8 CHIEF JUDGE BUMB: Okay.

9 MR. SLATER: I think that's most of it. And I know
10 that the defense has said they intend to bring some people
11 live. So I certainly won't speak for the defense, but that's
12 my understanding. And I know when we get to the motion there's
13 going to be some issues as to whether -- to what extent the
14 defense can play video of their own witnesses affirmatively as
15 opposed to bringing them in when they work for the company or
16 they're corporate representatives.

17 CHIEF JUDGE BUMB: All right. So let's just get to
18 it. How can I best help you? And what can I rule on?

19 MR. SLATER: Okay. On the designations, there's
20 really two parts to it.

21 CHIEF JUDGE BUMB: Okay.

22 MR. SLATER: One part has to do with what the defense
23 can play in their own case. And we've briefed in terms of
24 whether or not a witness should have to come in live or whether
25 they should be able to be played on video when it's your own

1 witness.

2 And our view is that if the witness works for the
3 company or affirmatively worked for the company and is
4 represented by the company and appeared for their depositions
5 and was deposed but represented by corporate lawyers that are
6 representing the company in the case, that they're available
7 based on all the case law.

8 CHIEF JUDGE BUMB: No; they are. And so can we just
9 deal in names now?

10 MR. SLATER: I don't have a list of names. And my
11 hope is this, Your Honor, with this motion --

12 CHIEF JUDGE BUMB: Wait. I thought you did have a
13 list of names.

14 MR. SLATER: I don't think we listed all the
15 different witnesses.

16 CHIEF JUDGE BUMB: Well, I have -- I mean, I've made
17 notes. I've made notes of Ge, Karlsson, Lin, Nassall.

18 MR. SLATER: Ah, I'm sorry. Yes, I didn't realize, I
19 was thinking of something else. Yes. These are the witnesses
20 that they designated for, yes.

21 CHIEF JUDGE BUMB: Yeah. And so I have all kinds of
22 notes up here to myself about why some of these people can't
23 come in live. And they're going to come in live, so who do you
24 want me to talk about first?

25 MR. SLATER: It's up to the Court. I mean, from our

1 perspective, they should all have to come in live.

2 CHIEF JUDGE BUMB: Okay. Let's go line by line.

3 The first one you have in your motion is Ge. Am I
4 saying that name correctly?

5 MR. SLATER: Jucai Ge, I believe.

6 CHIEF JUDGE BUMB: What?

7 MR. SLATER: Jucai. It's J-U-C-A-I, G-E.

8 CHIEF JUDGE BUMB: Yeah. So?

9 MR. SLATER: She's employed by the company. She's a
10 corporate representative. She appeared in depositions.

11 CHIEF JUDGE BUMB: So she's coming in live, right?
12 Is she their 30(b)(6)?

13 MR. SLATER: Yes.

14 CHIEF JUDGE BUMB: Okay. So she'll come in live.

15 MS. ROSE: Yes, Your Honor.

16 CHIEF JUDGE BUMB: Okay. They agree. That resolves.
17 Okay. Teva, Karlsson, Stefan Karlsson. Ex-employee
18 who lives in Sweden, right?

19 MR. STANOCH: Your Honor, I believe Karlsson is a
20 current employee. Lives in Europe.

21 MS. LOCKARD: He's an ex-employee.

22 CHIEF JUDGE BUMB: That's what my notes show, he's an
23 ex-employee.

24 MR. STANOCH: At the time of when this occurred he
25 was an employee, Your Honor.

1 CHIEF JUDGE BUMB: Oh.

2 MR. STANOCH: And he appeared for a 30(b)(1)
3 deposition and represented by Teva's counsel in this
4 litigation.

5 CHIEF JUDGE BUMB: Okay. Why can't he come in, in
6 person, Ms. Lockard?

7 MS. LOCKARD: We have not made any representation
8 that he cannot. Our position is that plaintiffs have requested
9 live -- that we bring in the live witnesses, the 31 or
10 30-something witnesses from these companies. And I think there
11 is a practical question that needs to be addressed. They have
12 designated 40 video depositions, and they are demanding to
13 bring in over 30-something live witnesses.

14 CHIEF JUDGE BUMB: Well, that's not going to happen.
15 So we're working on it.

16 So what about Karlsson?

17 MS. LOCKARD: So Karlsson is in Sweden.

18 CHIEF JUDGE BUMB: Right.

19 MS. LOCKARD: We could very likely get him here if we
20 need him to testify.

21 CHIEF JUDGE BUMB: Yeah. Well, he was the associate
22 director of API, so it seems like he's a -- he's an
23 ex-employee, right? So it seems like he's a pretty significant
24 witness, so he should come live.

25 MS. LOCKARD: He's an ex-employee, so I don't know

1 that we have the control to bring him. He is no longer
2 employed by Teva.

3 CHIEF JUDGE BUMB: I know. But you haven't even
4 asked him yet. So you'll ask him very gently. And then if the
5 Court has to get involved, you'll ask him again.

6 MS. LOCKARD: Fair enough.

7 CHIEF JUDGE BUMB: Okay. Pan Lin.

8 MR. STANOCH: He was one of the auditors for Teva
9 that physically inspected the ZHP facility that made valsartan
10 API.

11 CHIEF JUDGE BUMB: And he's in China?

12 MR. STANOCH: Yeah. That's my understanding, yes.

13 CHIEF JUDGE BUMB: Okay.

14 MR. HARKINS: Apologies. Who was the witness
15 referenced, Your Honor?

16 CHIEF JUDGE BUMB: Pan Lin.

17 MR. HARKINS: Your Honor, and I think it's probably
18 helpful as we work through the Teva witnesses, the
19 representations that were made to us in preparing for the March
20 trial date were that plaintiffs did not wish to actually bring
21 a single Teva witness live during their case.

22 CHIEF JUDGE BUMB: Why are you changing your mind,
23 Mr. Stanoch?

24 MR. STANOCH: Well, Your Honor, this motion is about
25 affirmative designations they're making of their own people.

1 They want to put in designations. And our position is, if they
2 want to call one of their witnesses, then they have the ability
3 under the rules and should have that person come in live.
4 There's no exception.

5 CHIEF JUDGE BUMB: So here's -- what I'm not going to
6 do, so everyone is very, very clear, is I am not going to spend
7 days and days and days of going back and forth between
8 designations and cross-designations and rebuttal designations;
9 I'm not doing it.

10 What I'm doing is I'm telling you to bring the
11 witness in live, unless you give me a good reason why you
12 can't.

13 Or, I may permit, the rules will permit me to have
14 live video testimony, which I'm reluctant to do because I have
15 to find extraordinary circumstances. I think that's what the
16 phrase is, which I can do.

17 But what I'm not going to do is I'm not going to get
18 reams and reams of papers and you folks are going to have me go
19 line by line through the depositions and say, well, the jury
20 heard this, now they have to hear this. It becomes very
21 confusing for a jury. Jurors don't like it. They really don't
22 like it, and I'm just not going to do it.

23 So, yes.

24 MR. SLATER: I definitely was not looking to
25 interrupt Your Honor. But what I was going to suggest before

1 is this: Our hope was that at the end of today, and it's
2 happening already, we're getting tremendous guidance from the
3 Court on substantive issues, the process of negotiating the
4 designations has been -- was in the works for months before the
5 trial date that got postponed.

6 CHIEF JUDGE BUMB: You want me to just be quiet; you
7 folks will work it out?

8 MR. SLATER: I don't want you to be quiet, no. What
9 I'm saying is, I think that the guidance you're giving us will
10 help us to resume those negotiations and narrow the disputes
11 significantly.

12 I think everyone in this room is practical enough to
13 know that if you say in an in-limine motion this is not coming
14 in --

15 CHIEF JUDGE BUMB: Okay.

16 MR. SLATER: -- that we now know, okay, when we go
17 through the designations, well, a witness is saying what Your
18 Honor precluded, we know that's coming out. We're not going to
19 waste the Court's time.

20 CHIEF JUDGE BUMB: Okay. But --

21 MR. SLATER: So --

22 CHIEF JUDGE BUMB: Okay. Fair enough. But I want
23 the witness here live, unless you tell me there's a really
24 good -- look, if you don't have -- I understand, I understand
25 what the rules are. I also have the discretion under Rule 611

1 to control the mode of interrogation. I think that if the
2 party can make a good-faith effort to get the witness here,
3 they should, the parties should.

4 I want the live testimony. I want as little
5 deposition testimony as possible. Jurors don't like it, and I
6 certainly don't want to spend my time resolving disputes with
7 you folks over depositions, you know, what comes in, what comes
8 out.

9 I'll say this, however: If the deposition is fairly
10 short in length and the parties have worked it out and they
11 don't need to involve the Court and have the Court intervene,
12 then I'll permit it, okay?

13 But the more I hear quibbling about we can't agree on
14 it, then I'm probably just going to throw my hands up and say
15 bring the witness in live.

16 MR. SLATER: From -- if I could ask -- for the
17 plaintiffs, we took, for example, witnesses from ZHP's
18 depositions.

19 CHIEF JUDGE BUMB: Okay.

20 MR. SLATER: 30(b)(6) witnesses and others.

21 CHIEF JUDGE BUMB: Yes.

22 MR. SLATER: From our perspective, and a lot of these
23 were done through translators.

24 CHIEF JUDGE BUMB: Oh, that's right. Yes.

25 MR. SLATER: So the --

1 CHIEF JUDGE BUMB: And there is an issue on the
2 translations, too. Or, no, that's something else. That's
3 another -- like an email, I think. Yes, go ahead.

4 MR. SLATER: So our position is, in terms of using
5 testimony of defense witnesses that we have deposed, that we
6 should be allowed to use those designated pieces of the
7 deposition. And what we expect would happen is we are going to
8 negotiate it.

9 CHIEF JUDGE BUMB: Yes.

10 MR. SLATER: We're going to narrow the disputes to
11 very little. If there's something we can't resolve, what I
12 would suggest is perhaps, and Ms. Rose and I had negotiated a
13 lot, so we had suggested to one another that maybe once we get
14 through everything or through a lot, that maybe we can pick a
15 witness and say, okay, this crystallizes a couple of our
16 remaining disputes, like one witness. Perhaps bring it to Your
17 Honor for a hearing on that one witness at some point soon,
18 next month or two, and then Your Honor's rulings on that one
19 witness would be tremendous guidance for us to then go to the
20 rest of the witnesses say, okay, we know how the judge is
21 ruling on these things, we can get it done, because we believe
22 we have the right to put on affirmatively their admissions.

23 Also, in terms of efficiency, because we're using the
24 videos, we don't have to play all of the translation, and it's
25 a massive savings in time. It's already taking -- it's a long

1 time because there's translations that have to be read for part
2 of the video, so we're trying to make it as efficient as we
3 can. So I just wanted to clarify in terms of your ruling that
4 we still as plaintiffs, if we deposed a witness and have
5 admissions that we can use against the company, that we can
6 still use those videos.

7 CHIEF JUDGE BUMB: Yes.

8 MR. SLATER: Okay.

9 MS. ALLON: Your Honor, can I just clarify one thing?

10 CHIEF JUDGE BUMB: Yeah.

11 MS. ALLON: Because this is in dispute. So we have a
12 witness, Dr. Jaiswal. He's coming from India. He's going to
13 testify live in this trial. The plaintiffs' position is that
14 they can still play his deposition video.

15 CHIEF JUDGE BUMB: No.

16 MS. ALLON: I want it clarified that that's not
17 permitted. He's going to testify live.

18 MR. SLATER: Well, question.

19 CHIEF JUDGE BUMB: What? You have him live. We're
20 not going to play a deposition and a live. Not doing it. If
21 the --

22 MR. SLATER: Well, in our case we believe that we
23 have the right to present and to meet our burden of proof, to
24 present the case the way that we choose to.

25 MS. ALLON: And we'll make him available in the

1 plaintiffs' case-in-chief.

2 CHIEF JUDGE BUMB: He's available. Mr. Slater, he's
3 available. You're going to -- that's why I'm saying, if the
4 witness is available, it's live testimony. I'm not going to
5 let you then -- I know what you want to do. You want to play
6 the deposition transcript and the deposition testimony because
7 it came in exactly how you wanted it. You'll have the witness.
8 They'll make him available. You'll call the witness. If he or
9 she veers from your deposition transcript, that testimony, then
10 you got the deposition.

11 No, we're not going to do both.

12 MR. SLATER: We're -- we're not looking to do both.

13 CHIEF JUDGE BUMB: No. But you're looking to put the
14 deposition testimony in when the defendants are making the
15 witness available to you.

16 MR. SLATER: The reason they're making the witness
17 available is not necessarily because we got exactly what we
18 wanted. This is going to lengthen the case significantly if it
19 has to happen for a lot of witnesses, because we don't have to
20 go through the entire background and testimony. We're able
21 with the deposition designations to focus on what we needed and
22 to just focus on what the issues are.

23 CHIEF JUDGE BUMB: Well, so when you call him to the
24 stand, don't go through the background, just get right to it.

25 MR. SLATER: I think that also, I don't know that the

1 defense has the right to force us by bringing the witness, if
2 they don't like how the deposition went to say -- I get that we
3 can impeach, I get that we can use the deposition. But it's
4 not as effective as just playing the testimony. I think in
5 terms of efficiency --

6 CHIEF JUDGE BUMB: Mr. Slater, I don't want the jury
7 listening to deposition testimony. I want it live. And I --
8 you know, look, you've preserved your objection. But I don't
9 see how this Court -- it would be reversible error for this
10 Court to say, no, you have a witness, you're going to make
11 it -- this is a case the jury is -- I'm not so sure it's going
12 to be the most exciting case the jury has ever heard.

13 (Laughter.)

14 CHIEF JUDGE BUMB: So we're going to make it as
15 interesting as we possibly can. That's going to be through
16 live testimony.

17 You have the deposition testimony. You're going to
18 have it to be available to cross.

19 What would the error of this Court be; that somehow I
20 prevented the plaintiff from what? I don't see the error. I
21 don't see the err of the way.

22 MR. SLATER: I think the issue is that we have the
23 right to use a deposition of a party opponent as an admission.
24 And I think that, respectfully, I think that your ruling would
25 deprive us of an absolute right we have to use admissions from

1 corporate witnesses, including 30(b)(6) witnesses who have
2 testified for the company to use that deposition testimony as
3 evidence.

4 CHIEF JUDGE BUMB: Okay. Let's play this out.

5 The witness is on the stand. You ask the witness:
6 Was the light red? Yes, it was. Okay. That's the admission.

7 You ask the witness at the deposition: Was the light
8 red? Yes, it was. Tell me the difference.

9 MR. SLATER: In that very simple example, there is no
10 difference.

11 CHIEF JUDGE BUMB: Yeah.

12 MR. SLATER: But it would be obviously an admission
13 from the stand versus the deposition.

14 But the other thing is this, one of the reasons we
15 think it's very important to be able to use the testimony that
16 we got in those videos is because it allows us to know before
17 the trial what the evidence is going to be, because we know
18 this is the testimony the jury is going to get. So both sides
19 can open knowing this witness is going in, this is exactly the
20 testimony that's been agreed to or ruled on, and we know that's
21 what the trial is. We can prepare with that. We can open on
22 it, whereas if the witnesses are not going to be able to be put
23 on through their deposition, through their admissions, we have
24 to be more circumspect. We don't know what the witness is
25 going to say. We don't know how --

1 CHIEF JUDGE BUMB: But, by golly, if the witness
2 veers from his deposition, you're going to be the first one to
3 tell the jury.

4 MR. SLATER: I -- I realize -- and I know that it's
5 always the value of cross-examination, but we, frankly, feel
6 like to put our case in as clean as possible, if we have clean
7 testimony from witnesses, that it's actually much more
8 effective for us to just play the video. I respectfully
9 don't -- I usually play a lot of video in my trials. I've
10 generally not had issues with juries.

11 CHIEF JUDGE BUMB: It's all video testimony?

12 MR. SLATER: I'm sorry?

13 CHIEF JUDGE BUMB: It's all video?

14 MR. SLATER: The depositions are all on video. And,
15 again, especially, I can't speak to the witnesses from the
16 other companies, but for the ZHP witnesses, a large number of
17 them we had to go through translators. It will be
18 exponentially longer. We'll have to now deal with getting a
19 translator that both sides can agree and then check translators
20 and all that time.

21 CHIEF JUDGE BUMB: I hadn't thought about that. I
22 hadn't thought about that.

23 MS. LOCKARD: But, Your Honor, he's asking to have it
24 both ways. He wants to play the video in his portion of the
25 case. For all of these witnesses, there's translation on the

1 video. Those witnesses now, as Your Honor has ruled, will have
2 to come live in our portion of the case. He gets an
3 opportunity then to cross-examine, and there's more
4 translation. It effectively doubles the time. The jury has to
5 listen to all of these foreign witnesses come in here two
6 times, translations. I think --

7 MR. SLATER: But that's the point of the rules that
8 we cited in our brief, which that's how it's supposed to work.
9 If it's the other side's witness and you can use it as an
10 admission, you can use the deposition. And if the other side
11 wants to put that witness on, on something we didn't play or on
12 everything we did play, they can bring that witness in live.
13 That's their right. But that's the second part of our motion;
14 that they can't inject their own evidence into our case.

15 MS. ALLON: Well, Your Honor, I disagree with that.
16 And I've had the opposite experience of Mr. Slater, which is
17 every trial I've been in, in their roll as managing the trial
18 the judge has said, where a witness is live, we don't play the
19 video.

20 And we're not injecting anything into the plaintiffs'
21 case. The witness is available. The plaintiff calls the
22 witness. The plaintiff does the examination.

23 Now, I do think that we should be permitted to then
24 do an examination not confined in scope so we don't have the
25 witness testify twice. I think that's much more efficient.

1 Dr. Jaiswal, for example, is coming from India. I'd rather not
2 ask him to stay here for three weeks so he can testify twice.
3 The witness goes once. But the plaintiffs control the
4 examination.

5 CHIEF JUDGE BUMB: So let me back up. How many of
6 these witnesses have -- there's a translator? It's
7 simultaneous translation, I guess.

8 MS. ALLON: Dr. Jaiswal is not impacted. There's no
9 translation.

10 MR. SLATER: And there is the rub that we want to put
11 our case in the way that we designed it. And we have the
12 deposition testimony, put our case in the way we want to. And
13 then if the witness has to come in live and we're deprived of
14 or our right to use the deposition as an admission and to give
15 it to the jury the way it is, the defense now during our case
16 gets to question their witness which we do not want to happen.
17 We do not think it's fair to let the defense now question their
18 witness in our case unless we put the witness on live at our
19 own choice, at our own decision, because they're now going to
20 be able to start to put their case in during our case. That's
21 the value to the depositions for us.

22 We took them in a very particular way so we could
23 structure the case through them, because it was understanding
24 these witnesses would not be coming to court. They're around
25 the world.

1 And even if the witnesses were in Bayonne, we still
2 would have the right to play their video or if they were in
3 Cherry Hill under the rules. The rules say we're allowed to
4 use the depositions that way.

5 And I think that the defense doesn't have the right
6 to then inject their case into our case. And that's what would
7 end up happening.

8 CHIEF JUDGE BUMB: Well, the way that I typically do
9 it is that, so that the witness doesn't have to come back
10 twice, is that the jury is then instructed that this now is the
11 portion -- this is now the defendant's case. And the jury,
12 they're very smart. They take notes of it. And they bring the
13 testimony in and they follow the burden of proof with respect
14 to each party.

15 I want a list of all of the witnesses that are going
16 to be live. Let's just -- let's resolve it now. Who's live?
17 Who's available to be live?

18 MS. LOCKARD: Well, Your Honor, on behalf of Teva,
19 because we had agreed that we would not need to call these
20 witnesses live, we have not asked each and every one of them if
21 they can come. Availability also depends on when the trial is
22 set.

23 So, I mean, if -- if there's any utility to us being
24 able to go back and talk to our witnesses, getting the guidance
25 that we've now gotten from the Court, this may be something we

1 want to talk about and deal with -- I hate to postpone. I'm
2 really grateful that you're cutting through all of this, but
3 this may be something that we can make it a little easier on
4 the Court.

5 CHIEF JUDGE BUMB: Okay. Here's my ruling: If the
6 witness can be made available, whether it's through subpoena or
7 otherwise or simply a phone call, the witness should appear
8 live, okay? That's my ruling.

9 With respect to Mr. Slater's argument that he's
10 entitled to present his evidence in the way that he wants to, I
11 appreciate the argument. The Court is also, under Rule 611,
12 can control the mode of interrogation.

13 I think to present the testimony through live
14 testimony to the jury is -- particularly in a case of this
15 type -- is preferrable. Jurors are appreciative of it.

16 To the extent after the witness testifies you
17 believe, you, any side, for that matter, believe that it is not
18 a fair representation of what the deposition was, then you'll
19 be permitted to play that as long as it's not cumulative, okay?

20 So I don't see any other way to do it.

21 MR. BERNARDO: Your Honor, may I seek a point of
22 clarification? And we appreciate your guidance.

23 Sorry. My name is Richard Bernardo for ZHP.

24 As was already represented, appearing live may depend
25 upon a number of things. For international witnesses,

1 particularly timing. Does appearing live also include for
2 witnesses that may not be able to get here, appearing by Zoom
3 or other video conference needs?

4 CHIEF JUDGE BUMB: No. No.

5 MR. BERNARDO: Okay.

6 CHIEF JUDGE BUMB: Because then I think in the
7 balancing that I'm being asked to do, then I think it gets into
8 Mr. Slater's point, which is now it becomes less of an
9 efficient mode of interrogation, because now the witness isn't
10 live, now you've got remote and you're trying to work in the
11 interpretation of it, and that will become, I think, almost
12 impossible to do remote. Okay.

13 MR. BERNARDO: No. Understood. And I appreciate
14 that clarification.

15 CHIEF JUDGE BUMB: So by live, I mean live.

16 MS. ALLON: And, Your Honor, one clarification for
17 us. For the witnesses who are live, truly live, does the Court
18 agree that they will just testify once?

19 CHIEF JUDGE BUMB: The way it will go is that
20 plaintiff will then proceed with the witness, if it's the
21 plaintiff's witness. It will go through direct, cross,
22 redirect.

23 Then, if it's now a part of the defendant's case, I
24 instruct the jury that for the convenience of the parties they
25 will now hear from --

1 MS. ALLON: Dr. Jaiswal, yeah.

2 CHIEF JUDGE BUMB: -- from the defendant's part.

3 MS. ALLON: Okay. Thank you, Your Honor.

4 CHIEF JUDGE BUMB: Okay. Because the jurors are
5 taking notes, and they're putting in the column what the
6 defendants have introduced and then they're taking notes what
7 the plaintiffs have introduced.

8 Mr. Slater.

9 MR. SLATER: Your Honor, there's two things that I
10 just want to make clear. We're still going to have to work out
11 all of the designations even based on what you've said from the
12 bench, because we have to be ready to use those videos anyway.

13 CHIEF JUDGE BUMB: Yeah.

14 MR. SLATER: A lot of these witnesses are not going
15 to be available to come in person. We're still going to have
16 to work those out, and even for a witness --

17 CHIEF JUDGE BUMB: And it sounds like you can. It
18 sounds like you're going to be able to. Why can't you work
19 that out?

20 MR. SLATER: No. I'm saying I think -- there's
21 probably going to be a few disputes that -- like I suggested, I
22 think there's a streamlined way to get you maybe some samples
23 of some testimony that you could then rule on and then take
24 those -- those rulings.

25 CHIEF JUDGE BUMB: Well, give me a preview, just tell

1 me, give me a preview of what --

2 MR. SLATER: For example, testimony -- and you're
3 going to -- again, I said the MILs today getting ruled on is
4 going to be very helpful -- a witness talking about, you know,
5 there's no risk to this because of the dose because it wasn't
6 enough in the pill or something.

7 CHIEF JUDGE BUMB: Okay.

8 MR. SLATER: And if Your Honor -- now we're going to
9 get a ruling on whether or not general causation comes in, but
10 I'm coming up with an easy example.

11 CHIEF JUDGE BUMB: Okay.

12 MR. SLATER: Where we say, well, that shouldn't come
13 in and the defense says, well, it should.

14 There may be other issues where, for example, about
15 the FDA, depending on how the question is asked, where it may
16 be a close call, where we may have something that we couldn't
17 agree to.

18 CHIEF JUDGE BUMB: Well, maybe -- it sounds to me
19 that you can't agree to a lot of this because you don't really
20 know what's in, what's out.

21 MR. SLATER: Definitely, it's going to make -- it's
22 going to take the landscape down to a much smaller point.

23 CHIEF JUDGE BUMB: Okay. So I should stay tuned is
24 what you're saying.

25 I mean, you'll try to work it out. You're going to

1 have a live witness. You're then to prepare for if the live
2 witness kind of veers from the deposition, the testimony. Then
3 you're going to have a quarrel about what you can't agree on,
4 and then I'll have to resolve that, right?

5 MR. SLATER: You would have to resolve that if we
6 can't agree.

7 CHIEF JUDGE BUMB: Yeah.

8 MR. SLATER: And again --

9 CHIEF JUDGE BUMB: But you have -- it sounds like you
10 have disagreements now, but you're really disagreeing because
11 you don't know how I'm ruling on things.

12 MR. SLATER: I think that's probably 75 to 80 percent
13 of it.

14 CHIEF JUDGE BUMB: Oh. Well, then, I'm definitely
15 not going to do anything right yet.

16 MR. SLATER: And, again, I know I've said this, but
17 I'm just very concerned, I feel like to the extent that the
18 defense says, well, look, this video did not go well for us,
19 they have really good testimony, we're going to somehow get
20 this witness there and it's not going to be as clean, and even
21 if we use impeachment, et cetera, I'm very concerned that our
22 right under the rules -- I get -- I know what 611 says, but I
23 don't think that that can supersede the rule.

24 CHIEF JUDGE BUMB: Let me say this to you: If the
25 witness comes in and testifies and all of a sudden you simply

1 just don't recognize this witness because it's so different
2 from the testimony that you elicited, then you'll make that
3 argument to me and I probably will allow you to play it. But
4 this is not going -- this is not meant to be an opportunity for
5 the defendants to recast their witnesses or vice versa; that
6 all of a sudden, they've had a talking to and now they've just
7 changed their tune. That's just not going to happen. So if
8 that's what you're concerned about, I'll revisit my ruling.

9 MR. SLATER: Can we get a deadline really, really
10 soon?

11 CHIEF JUDGE BUMB: For?

12 MR. SLATER: For the defense to tell us which of the
13 witnesses that we have been dealing with these deposition
14 designations that we've requested are going to be available
15 live. I mean, we need to know that like ASAP because we have
16 to know --

17 CHIEF JUDGE BUMB: They're going to tell you in ten
18 days.

19 MR. SLATER: Okay.

20 MS. LOCKARD: Your Honor --

21 MS. ALLON: Well, I think --

22 (Multiple counsel stood up.)

23 (Laughter.)

24 MS. ALLON: The first step is --

25 CHIEF JUDGE BUMB: They're going to tell you in seven

1 days.

2 (Laughter.)

3 MS. ALLON: I think the first step is the plaintiffs
4 tell us who they want. They know for us.

5 CHIEF JUDGE BUMB: He did, in his motion. Well, all
6 right. That's fair. Just tell them.

7 MS. ALLON: Tell us who you want.

8 MR. SLATER: I think we did already. We've --

9 CHIEF JUDGE BUMB: They're in their motion. But
10 listen, by tomorrow tell them the witnesses you're interested
11 in knowing. They're in the motion, but --

12 MS. ALLON: We can go off the -- if that's the list.

13 MR. SLATER: Well, those witnesses that are listed on
14 page 1 of our brief are defense witnesses that the defense
15 wants to use video for instead of bringing them live for
16 themselves.

17 I don't believe that we gave you a list of all --
18 that's where my disconnect was at the start of the argument.

19 CHIEF JUDGE BUMB: Oh.

20 MR. SLATER: But they have that. We've been dealing
21 with it since last year. All the witnesses that we are
22 negotiating designations on, that's what we intend to play at
23 trial. They have -- and we also noticed a bunch --

24 CHIEF JUDGE BUMB: How many are there of those?

25 MR. SLATER: I can't say for Teva and Torrent. I

1 would say combined there's probably somewhere around 30
2 witnesses. Now, we obviously expect -- but we expect, Your
3 Honor, the following to happen:

4 As we get done with all these deposition designation
5 negotiations, any resolutions from the Court, we're now going
6 to say, okay, we have three different witnesses who said this,
7 we don't need three witnesses to say this.

8 CHIEF JUDGE BUMB: I know. It's going to go down to
9 about 10 or 15; I know.

10 You have a very important note in front of you.

11 MR. SLATER: The witnesses are listed in the pretrial
12 order.

13 CHIEF JUDGE BUMB: Okay.

14 MS. ALLON: That's right.

15 MS. LOCKARD: Correct. And we had received 40
16 deposition designations on defense from plaintiffs. That's the
17 number, 40.

18 The only thing -- the only reason I stood up is that,
19 and I understand Your Honor's ruling, some of these witnesses,
20 for example, Pan Lin, Teva witness from China, their travel
21 ability is going to be determined by the --

22 CHIEF JUDGE BUMB: Trial date?

23 MS. LOCKARD: -- visa, whether they can get a visa.

24 CHIEF JUDGE BUMB: Oh.

25 MS. LOCKARD: So, I mean, we won't do anything to

1 stand in the way of that. But if they don't get a visa granted
2 by their home country, I won't know that until --

3 CHIEF JUDGE BUMB: I think the best that you can do
4 is say these are the witnesses that we believe that we will be
5 able to secure their live attendance by. It's contingent upon
6 getting a visa, and then the parties will be prepared, be
7 prepared to go forward with the remote. I'm not going to delay
8 the trial.

9 MS. LOCKARD: Fair enough. I just wanted to make
10 that point about the visa, Your Honor.

11 CHIEF JUDGE BUMB: Okay. Yes.

12 MS. ALLON: So, Your Honor --

13 CHIEF JUDGE BUMB: Why did you all jump up? I don't
14 remember.

15 MS. ALLON: Yeah. This is about the timing, right?
16 So that's fine. If we're going to go off the joint pretrial
17 order, we're happy to let the plaintiffs know within seven days
18 who we're bringing live, seven, ten, whatever, either one.
19 Doesn't matter to Torrent. But then the plaintiffs need to
20 confirm for us in a reasonable amount of time who they would
21 like to call live in their case-in-chief, right? Because this
22 goes back to the issue of witnesses' schedule.

23 CHIEF JUDGE BUMB: Yeah.

24 MS. ALLON: So can we have a guideline for that?

25 MR. SLATER: I don't know that at this point we

1 should be placed in a position of deciding who we're going to
2 put on the witness stand. Obviously we have to give them
3 notice of whether the person has to come. Because, again,
4 we've obviously made our preference very clear and you
5 understand our preferences. We want to use the depositions.
6 We went through a massive process during COVID to get all these
7 depositions done with the intent of using them. So I think a
8 lot is going to depend on where the video negotiations end,
9 what Your Honor's rulings are, and our trial decisions as we
10 get closer.

11 That's, again, one of the benefits of us using the
12 video. We know what the testimony is. We know our strategy.
13 We know what's coming in. We don't have this kind of -- I'm
14 not saying this pejoratively, but sort of a shell game of
15 figuring out who's going to be available, when are they going
16 to be available, what are they going to say? I just felt for
17 efficiency and for taking a lot of pressure off everybody if we
18 know the videos are done in advance, it actually makes things
19 much easier because then it's done, everyone knows what they're
20 going to say.

21 And at the trial, I can tell you on our side, and
22 I've tried cases with some of the lawyers on the defense side,
23 these videos get played, there's no negotiating during the
24 trial, it's done before. They're packaged, both sides have
25 them. Both sides have the scripts. Both sides have the

1 videos. Everybody knows. All the objections are done. So
2 Your Honor just says "next witness," and we would say we have,
3 you know, Jane Smith, we're going to present by video. She was
4 the quality assurance director of X, Y, Z, and we play it, and
5 it's smooth. We already know the exhibits. The exhibits are
6 marked. Everybody knows what is going on.

7 CHIEF JUDGE BUMB: Am I making more of this than I
8 need to be? Who are the witnesses that the defendants want to
9 call to be live?

10 MS. ALLON: So for Torrent, we're calling two
11 witnesses live: Dr. Jaiswal and Ms. Ge. That's it.

12 CHIEF JUDGE BUMB: What about the others?

13 MS. DAVIDSON: For ZHP, we are formatively intending
14 to call three of our witnesses live. We are absolutely going
15 to go back, in light of what Your Honor said today, and try to
16 get visas expedited, visa applications, for the remaining
17 witnesses. There are like, I think, over ten. So it will take
18 some work.

19 MR. SLATER: It has to be at least 10 or 15.

20 MS. DAVIDSON: Correct.

21 MR. SLATER: Not that they're all the same length,
22 and the videos will be cut down for trial obviously. We're
23 very mindful of not being repetitive. I know the Court doesn't
24 want repetitive testimony. We're mindful of the jury.

25 CHIEF JUDGE BUMB: For Teva?

1 MR. HARKINS: Your Honor, we're intending to call
2 three witnesses live during our case-in-chief.

3 MR. SLATER: Who are the three witnesses for ZHP? I
4 know you said -- I think it's Jucai Ge, right, is one?

5 MS. DAVIDSON: Jucai Ge, Maggie Kong, and Jinsheng
6 Lin, the email author.

7 MR. SLATER: Oh, right. We have a motion on that, in
8 the trial brief.

9 MR. STANOCH: And, Your Honor, if we may ask the same
10 question for the Teva three.

11 MS. LOCKARD: Well, that depends a lot on how the
12 motions in limine rulings come out. But our objective is to
13 try to keep the number of witnesses limited to three for
14 efficiency's sake.

15 MS. ALLON: And my point, Your Honor, is not to
16 overcomplicate anything, and we do this in every trial, at some
17 point in time they have to tell us do they want those witnesses
18 in their case-in-chief or not. And accounting for the fact
19 that many of these are coming from very far away, it will be
20 helpful to know are they going to go in the first week of
21 November or are they going to go in the third week of November.
22 That's all. I'm just asking for a reasonable time period when
23 the plaintiffs --

24 CHIEF JUDGE BUMB: Yeah. Well, we'll get there.
25 They'll do that.

1 MR. SLATER: I'm a little perhaps confused or maybe
2 missing it, but my assumption was that the party -- the
3 witnesses the defense intends to bring live, those would be the
4 ones that we have this issue with. The ones they don't intend
5 to bring live, we should get the videos done for them. That
6 was my understanding. I'm not sure --

7 MS. ALLON: Yeah. I'm in agreement. I just want to
8 know for the live witnesses, are you calling them in your
9 case-in-chief or not?

10 CHIEF JUDGE BUMB: Okay. I think --

11 MR. SLATER: Your three live witnesses.

12 MS. ALLON: Yeah.

13 CHIEF JUDGE BUMB: I think we're all getting a
14 little -- and maybe I contributed to it.

15 MR. SLATER: Trial lawyer paranoia?

16 MS. ALLON: I think we just resolved it, Mr. Slater
17 and I.

18 MS. DAVIDSON: Your Honor, may I raise a few more
19 points?

20 (Counsel conferring.)

21 CHIEF JUDGE BUMB: Okay.

22 MS. DAVIDSON: One of the problems we have with these
23 designations --

24 THE COURT REPORTER: Counsel, I'm sorry, can you get
25 closer to the microphone?

1 MS. DAVIDSON: One of the issues we have with these
2 designations is that the way plaintiffs want to cut them cuts
3 off the answers in the middle. And that points exactly to why
4 live testimony is much more appropriate because of the
5 chopiness of it.

6 So while, you know, Adam is very optimistic about how
7 well these videos will play, we have a lot of issues with the
8 way they're being spliced. And there will be --

9 CHIEF JUDGE BUMB: So that's where I started, which
10 is, what I will not do is spend days and days and days of going
11 through and determining what got cut off, what should come in
12 under the doctrine of completeness. I'm not going to do that.
13 It is an incredible amount of resources that are unnecessarily
14 spent if the witness were here live, okay?

15 And so that's why I have said that every effort
16 should be made for the witnesses who are going to be
17 testifying, whether it's the plaintiffs' witnesses or the
18 defendants' witnesses, to have that witness here live. I know
19 that's not what the plaintiff wants. The plaintiff wants to be
20 able to put its case in in a systematic way. But that calls
21 for the Court to do exactly what it does not want to do and
22 will not do. Because it gets back to this back-and-forth of
23 the parties quarreling over every little line. And I'm just
24 not going to do it.

25 So what my ruling is, is that the parties must make

1 every effort to call their witnesses live and advise the Court
2 that they have made every good-faith effort to do so. And I
3 will rely upon the good faith of the lawyers to do that.

4 If it can't be done, then the remote testimony will
5 come in -- or the deposition video testimony will come in, and
6 I'll have to, you know, roll up my sleeves and resolve your
7 disputes.

8 So that's my ruling. You folks work it out.
9 Mr. Slater, you say who you can secure live. Defendants, you
10 tell Mr. Slater who you can secure live, and we work backwards
11 or forwards.

12 MR. SLATER: And just to give you a little more
13 comfort on the issue that Ms. Davidson just raised, that's the
14 second half of our motion, obviously, the completeness issue.

15 I don't think that's actually a giant problem,
16 because once Your Honor rules on three or four of those or if
17 Judge Vanaskie rules on three or four of those, the issue is
18 obviously when we ask a question and say did you know on this
19 date that this letter was sent -- I'm making up an example --
20 and the witness says, yes, but of course that letter doesn't
21 matter because the FDA did X, Y, Z and we knew this and we knew
22 that, so obviously we were directed not to say move to strike
23 on the record, but we obviously feel that the nonresponsive
24 part would come out. That's straightforward trial law stuff.

25 CHIEF JUDGE BUMB: If you folks come to me and say

1 here is the testimony, we don't have any objections to it, and
2 Judge, you don't have to rule on any of this and so can we not
3 call the person live, I'll reconsider.

4 MR. SLATER: If we do have any disputes, would it be
5 better if we bring them in a sampling to either Your Honor or
6 Judge Vanaskie?

7 CHIEF JUDGE BUMB: Judge Vanaskie will handle it.

8 MR. SLATER: Okay. Because maybe if we're ordered to
9 start to maybe in 30 days give a sample to Judge Vanaskie, we
10 can maybe narrow down a few.

11 CHIEF JUDGE BUMB: I'll let you do that. But if I
12 see that you folks are burdening Judge Vanaskie and it's a
13 little bit of an end-run around my ruling, then I'm going to
14 tell Judge Vanaskie not to do it. I'm going to ask Judge
15 Vanaskie not to do it.

16 MR. SLATER: We only run up the middle, Judge, never
17 around the end.

18 CHIEF JUDGE BUMB: Yeah. Okay. And I'll keep a
19 vigilant eye.

20 Yes.

21 MS. DAVIDSON: Your Honor, at the risk of belaboring
22 this, obviously we don't agree that one or two aren't
23 representative of them all. Any time a question is asked,
24 where the appropriate end of that question is depends on the
25 context of that question. It's not like it can be something

1 that's extrapolated.

2 CHIEF JUDGE BUMB: I know. But you're just
3 illustrating why I want live testimony. But by the same token,
4 I don't want, you know, let's just argue about it for the sake
5 of argument so we have to bring the witness in live. That I'm
6 not going to tolerate either. You folks are just going to have
7 to work it out.

8 MR. SLATER: But obviously if the witness is on the
9 stand, if the witnesses did what I just said, I would assume
10 Your Honor would say: If the question calls for a yes or no,
11 answer it with a yes or no.

12 CHIEF JUDGE BUMB: Yeah.

13 MR. SLATER: Your lawyer can ask a question later.
14 To us it's a straightforward thing. But we're certainly not
15 going to belabor it. Hopefully we'll work through it.

16 CHIEF JUDGE BUMB: Okay. Let's see how it goes. You
17 know my framework, okay?

18 MR. SLATER: Thank you, Judge.

19 MS. DAVIDSON: Understood. Thank you, Your Honor.

20 CHIEF JUDGE BUMB: All right. 2648. Are these --
21 okay. Let me see. What's the one -- what docket number is the
22 one that -- I just want to get some rulings on some of this.
23 The docket number where Judge Vanaskie ruled on the -- I can't
24 find the docket number -- on the champerty defense, to amend
25 the answer.

1 MR. MARTIN: I believe it's 2672, Your Honor.

2 CHIEF JUDGE BUMB: Can you say that again?

3 MS. LOCKARD: 2672.

4 MR. MARTIN: 2672, Your Honor, I believe.

5 MS. DAVIDSON: Your Honor, would you like to hear
6 argument on that before we get to that MILs?

7 CHIEF JUDGE BUMB: I was going to give you my ruling.
8 Do you want to argue it?

9 MS. DAVIDSON: We did bring an associate who probably
10 wants at least two minutes of fame.

11 MR. MARTIN: Thank you, Your Honor. I'll let you
12 start with your preliminary thoughts and then I'm happy to
13 answer any questions.

14 CHIEF JUDGE BUMB: I don't want to do that to you.
15 (Laughter.)

16 MR. MARTIN: I'll keep it brief, Your Honor.

17 CHIEF JUDGE BUMB: Go ahead, put your name on the
18 record.

19 MR. MARTIN: I'm sorry. Zachary Martin for the ZHP
20 Defendants.

21 Our view is that Judge Vanaskie erred in two
22 fundamental ways. The first and I think most fundamental is
23 the prejudice issue. Judge Vanaskie, respectfully, repeatedly
24 referenced us being on the eve of trial. And we are not
25 anymore. We now have no trial date. But Your Honor has

1 suggested November, which is four months from now. It's eight
2 months from when we initially filed this motion for leave.
3 That's actually a longer distance of time than the time between
4 when our answer was initially due in December and the initial
5 trial date in March.

6 So in terms of talking about prejudice to the
7 opposing party or to the Court, there's actually more time to
8 deal with these issues now than there would have been if we
9 raised them in the answer.

10 There may be difficulties, but if there are
11 difficulties, they stem from the existence of the defenses and
12 from perhaps the Court's schedule rather than from any
13 tardiness on our part in asserting them. And that's not the
14 kind of prejudice that the amendment rules deal with.

15 If I can touch briefly on the merits, starting with
16 New York, which is the governing law for one of the
17 assignments, Judge Vanaskie suggested that because these are
18 large, sort of, omnibus assignments that didn't relate
19 specifically to valsartan, they don't implicate the champerty
20 rule.

21 Respectfully, I don't think that's a distinction that
22 I see anywhere in Section 489 of the judiciary law or in the
23 cases applying it. And I would suggest that if the public
24 policy issue has to do with not trading in lawsuits, trading in
25 many at once is just as bad as trading in one.

1 Turning to Ohio, I don't think we need to get into
2 champerty per se, because I think there is a much more
3 straightforward rule that comes out of *West Broad Chiropractic*,
4 and a couple of the auto body shop cases that we cited in our
5 brief, which is that if you haven't established liability and
6 damages, you can't assign the right to recover for them. That
7 is idiosyncratic. It's not the rule in most states. But the
8 Ohio courts have been very, very clear about that. And
9 frankly, it's up to the Ohio courts and not a federal court in
10 diversity to make that policy judgment.

11 So those would be our arguments for why we think
12 Judge Vanaskie respectfully erred. And I'm happy to answer any
13 questions you have.

14 CHIEF JUDGE BUMB: You don't think the revised code
15 abrogated the *Rancman* decision?

16 MR. MARTIN: So it -- I would say that --

17 CHIEF JUDGE BUMB: Or at least complicated it. You
18 agree with me on that?

19 MR. MARTIN: I would say it is complicated with
20 respect to the champerty -- with respect to champerty, which
21 I'm separating from which is the *Rancman* decision and the cases
22 that followed that.

23 I'm separating that from what we call in our papers
24 assignment of contingent future interests, which is the *West*
25 *Broad Chiropractic* case and the *3C and Blue Ash Auto Body*

1 cases. All of those cases postdate the 2008 enactment of the
2 statute. So I think it's very clear that the statute doesn't
3 abrogate that line of cases, even if it does -- and I would
4 disagree that it abrogates the *Rancman* line of cases, but I
5 would agree with you, that is a more complicated question. The
6 other line of cases entirely postdates the statute.

7 CHIEF JUDGE BUMB: Okay. All right. Thank you,
8 Mr. Martin.

9 Anybody want to respond over here?

10 MR. NIGH: Your Honor, I would just respond to the
11 argument related to Ohio. In order for them to make that
12 argument work, they have to characterize these assignments as
13 contingent future interests primarily. That's not what they
14 are. The assignments are very clear. They're assigning the
15 existing rights that the assignor had at the time of the
16 assignment.

17 So, for example, Medicare Secondary Payer Act --
18 that's where the MSP name comes from -- their whole purpose is
19 not to go and file lawsuits against every single person.
20 They're not assigning a lawsuit. What they are doing is
21 they're assigning the rights that when, for example, MSP -- or
22 when the assignor pays, you know, insurance benefits, and there
23 should have been another payer that was the primary payer so
24 that the assignor shouldn't have had to pay, it's assigning the
25 right to be able to go after the other primary payer.

1 So, for example, if there's a car accident, in a car
2 accident the primary payer is not these assignors. The primary
3 payer would be the car insurance.

4 And so if these assignors paid those benefits and not
5 the car insurer, well, the assignors would have the right to be
6 able -- present right, not some future right, they have the
7 present right to be able to go back after the car insurance
8 company to be able to get their money back. That's the primary
9 intent of this. That's why the name of the party is "MSP."

10 And the whole idea on this primary under New York
11 law, it has to be the primary purpose, the assignments happened
12 before there was ever a recall in play. Like, these
13 assignments happened in 2017 and before. So there was -- the
14 only person -- the only parties that actually knew that there
15 was a contamination of NDMA at that time, ZHP. I don't know if
16 any other -- I don't know if Torrent and Teva. We don't have
17 information of that. ZHP is the only one that knows that this
18 product is contaminated with NDMA. So those assignments that
19 happened in 2017 were not with the intention of litigation
20 against ZHP in this case.

21 CHIEF JUDGE BUMB: And is that the discovery I would
22 have to allow?

23 MR. NIGH: Yes.

24 CHIEF JUDGE BUMB: If I didn't agree with Judge
25 Vanaskie, what discovery would need to be -- I guess I should

1 ask that of Mr. Martin. What discovery would need to be had?

2 MR. MARTIN: So I think it's relatively little. So I
3 think on the Ohio point, I can't think of much discovery at
4 all. It's the nature of the assignment. And I will just be
5 very brief. But I think the automobile example is a good one
6 because that's exactly what the cases we cite in our brief
7 are -- someone injured in an automobile accident who assigns
8 their right to recover against the tortfeasor's auto insurer.

9 But to answer your question directly, for the Ohio --
10 for the Ohio issue, I don't foresee a lot of discovery. New
11 York law does turn on the primary purpose, and there might be
12 discovery into that. But the critical point is that discovery
13 was closed at the time our answer was due. So if there is
14 additional discovery, which I don't necessarily think would be
15 a lot, it would not -- the fact of reopening discovery isn't
16 any different now than it would have been in December.

17 CHIEF JUDGE BUMB: What is the time frame between the
18 time that discovery was closed by the time your answer was due?

19 MR. MARTIN: Our answer was due in December of last
20 year. I -- if you'll give me one second, I really apologize,
21 Your Honor, if I can consult with my colleagues.

22 CHIEF JUDGE BUMB: Yeah.

23 (Counsel conferring.)

24 MR. OSTFELD: June 2021.

25 MR. MARTIN: June of 2021. So there were two years,

1 two and a half years between the end of discovery and the
2 answer. And that's really sort of the unique thing about the
3 filing of an answer in a bellwether case in an MDL. So no
4 difference in terms of discovery if we had done this in
5 December, if we did this in March.

6 And the other thing, Your Honor, I'm sorry, is -- I
7 really apologize, Your Honor -- is that if Your Honor believes
8 discovery in some way needs to be limited or costs need to be
9 shifted to us in order to mitigate prejudice that you see, that
10 is something that it would certainly be within your discretion
11 to order. And I don't think we would push back on that.

12 CHIEF JUDGE BUMB: Okay. Mr. Nigh.

13 MR. NIGH: Your Honor, with the amount of work that
14 we have to do, four months is a snap of the fingers. So this
15 idea that there wasn't prejudice, clearly there was. I didn't
16 come back to that part. And the other thing, and we haven't
17 heard the entire time, there were all these different times
18 that they could have brought the motion to amend. They could
19 have done it in their initial answer. They could have done it
20 in their motion for summary judgment, they could have done it
21 in their first amended answer, and they could have done it in
22 their motion to certify. They did not do it. And we have yet
23 to hear one reason of an excuse for why they did not. It does
24 prejudice us. We've laid that out in our papers.

25 MR. MARTIN: So if I can respond to that, briefly.

1 Rule 15 doesn't have the good cause standard that
2 Rule 16 does in it. It does consider undue delay. But the
3 cases are very, very clear that delay alone is not enough, and
4 nor is the fact that maybe we should have done this earlier.

5 I'm not going to say that we shouldn't have included
6 this in our answer, but there are several cases cited in our
7 papers, including *Heyl*, a case out of the Virgin Islands in the
8 Third Circuit, which is quoting a Supreme Court case that says
9 the point of this isn't to punish counsel for mistakes, it's
10 not to award good lawyering or punish bad lawyering. It's to
11 promote resolution on the merits to the extent possible without
12 prejudicing the opposing party.

13 And I understand that four months is not a long time,
14 but the time between December and the initial trial date in
15 March was three months. So, again, there's no difference -- in
16 fact, it is more time as I think I've said earlier than it
17 would have been if things had gone according to the original
18 schedule.

19 CHIEF JUDGE BUMB: Okay. All right. Thank you.

20 So here's my ruling: I think that Judge Vanaskie got
21 it right. I do think that it's come too late, the motion for
22 leave to amend. It simply comes too late.

23 I look at this issue and I say there is discovery to
24 be had. There would have to be discovery as to the primary
25 purpose under New York law.

1 Under Ohio law, I agree with what Judge Vanaskie -- I
2 don't know that he ruled it, but certainly questioned it. I do
3 think that the revised code probably did abrogate the decision.
4 And what I find interesting about it is that there are all
5 these factors to look at under the revised code, such as, you
6 know, did the lawyers review the contract, did they determine
7 the costs and the fees were disclosed, et cetera, et cetera.
8 There's all these factors that the revised code says have to be
9 done. Why do I say that? Because discovery would have to be
10 had on those issues. And we are months away from a trial. And
11 so I'm not going to let it digress into discovery on these two
12 issues.

13 So for those reasons, I'm going to dismiss the
14 appeal. I think that Judge Vanaskie got it right, okay? Thank
15 you, counsel.

16 MR. MARTIN: Thank you, Your Honor.

17 CHIEF JUDGE BUMB: All right. So the motion for
18 sanctions, I know Judge Vanaskie just ruled yesterday, so
19 you've heard, right? On the adverse inferences. We'll maybe
20 get to that a little bit later. I haven't focused too much on
21 that because it just came in.

22 Where did I leave off? Two-six.

23 MR. OSTFELD: Four-seven.

24 CHIEF JUDGE BUMB: Four-seven? No.

25 JUDGE VANASKIE: 2648.

1 CHIEF JUDGE BUMB: 2648. Motion in limine by MSP
2 Recovery Claims, okay. These are the long ones, right? And
3 then 2649. What is 2649?

4 MS. ALLON: This is the defendants' motions in
5 limine, Your Honor.

6 CHIEF JUDGE BUMB: Yes. All right. We're going to
7 break around 1:00. So let's get to some of these issues.

8 Where is the -- as I told you folks in the beginning,
9 I deal with docket numbers, so it's somewhat confusing. Where
10 was the issue with respect to the motion where, concededly, I
11 think Judge Kugler was looking at the expert report for the
12 certification?

13 MR. HARKINS: Your Honor, that is docket 2632,
14 plaintiffs' motion on that amended expert report.

15 CHIEF JUDGE BUMB: 2632.

16 (Counsel conferring.)

17 CHIEF JUDGE BUMB: Loretta.

18 (Discussion was held off the record.)

19 CHIEF JUDGE BUMB: You all remain seated. I'll be
20 right back. Because I'd like to just resolve those, too,
21 because I know I've got notes. But I must not have them here.
22 Don't go anywhere. I'll be right back.

23 (Recess was taken at 12:39 p.m. until 12:43 p.m.)

24 CHIEF JUDGE BUMB: You can have a seat. Thank you
25 all.

1 All right. I knew I was missing motions. Here they
2 are.

3 2592, that's it. 2592.

4 Okay. Motion to Amend/Correct the Opinion on
5 Liability Expert Reports. Yes. Yeah.

6 So, yes, I've reviewed all of this, and I'm going to
7 tell you how to modify my ruling and then you all tell me. You
8 want to hear my ruling first and then you tell me if I'm wrong?

9 MR. STANOCH: Yes.

10 (Laughter.)

11 CHIEF JUDGE BUMB: Because -- so I'm going to work
12 from Judge Kugler's Opinion, his Order vacating. Let's see.
13 I'm now looking at the Anderson report, okay.

14 MR. STANOCH: Uh-huh.

15 CHIEF JUDGE BUMB: Because some of it comes in.

16 MR. STANOCH: Uh-huh.

17 CHIEF JUDGE BUMB: So paragraph 20, I think part of
18 it comes in. The last sentence doesn't. "Based upon the
19 information made available to Teva, Teva could not have
20 reasonably foreseen that the API purchased from ZHP and used to
21 manufacture would contain NDMA." That's a jury question. But
22 the other part of the paragraph comes in.

23 Number 21 is out.

24 Twenty-two is fine.

25 MR. STANOCH: I'm sorry, in or out, Judge, when you

1 say "fine"?

2 CHIEF JUDGE BUMB: It's -- yeah.

3 MR. STANOCH: Sorry.

4 CHIEF JUDGE BUMB: It can come in. It can go before
5 the jury.

6 MR. SLATER: Okay. Thank you.

7 CHIEF JUDGE BUMB: I had a question about 25 and 26.
8 Based -- and I don't know who can answer this for me -- based
9 upon competency.

10 MR. HARKINS: Apologies, Your Honor. The phrase
11 "based upon competency"?

12 CHIEF JUDGE BUMB: How does he know? How does
13 Anderson -- what's his competency to know those two statements,
14 25 and 26?

15 MR. HARKINS: And I apologize. I need to get the 25
16 and 26 language in front of me.

17 CHIEF JUDGE BUMB: So my questions relate to 25, 26
18 and 27.

19 So I'll keep going on.

20 MR. STANOCH: Uh-huh.

21 CHIEF JUDGE BUMB: Forty-nine I think comes in.

22 This is the brief that, am I right, this is the -- is
23 this the goose-and-gander brief?

24 MR. HARKINS: No, Your Honor. That's why I think
25 that might be some of the confusion.

1 MR. STANOCH: Yes, I think that's -- I agree with
2 Mr. Harkins.

3 CHIEF JUDGE BUMB: Okay. Which one's the
4 goose/gander?

5 MS. ROSE: Your Honor, I believe that's the motion
6 with respect to Dr. Ali Afnan. There's a motion and a
7 cross-motion.

8 CHIEF JUDGE BUMB: Yeah. That's 2591. That's my
9 next one. Okay.

10 Well, I did -- is this the one where Judge Kugler
11 confused the reports?

12 MR. STANOCH: Yes, Your Honor.

13 CHIEF JUDGE BUMB: Yeah. Okay. All right.

14 MR. STANOCH: And our only point -- I mean, we
15 certainly filed this. We don't want to belabor it. We
16 certainly had these two things in our motion.

17 CHIEF JUDGE BUMB: No, I know. And actually, when I
18 looked, when I went through the papers for both, I thought that
19 both of you were right and both of you were wrong. That's why
20 I'm giving you my ruling now. I think that some of this comes
21 in and some of it doesn't.

22 MR. STANOCH: Okay.

23 MR. HARKINS: Your Honor, to answer the question with
24 respect to 25 and 27.

25 CHIEF JUDGE BUMB: Yeah.

1 MR. HARKINS: The competency that Mr. Anderson brings
2 to make those statements is simply his experience working with
3 the FDA, working as a consultant, evaluating this material, and
4 we understand that he would not be opining on or putting
5 himself in the shoes of the FDA talking about ultimate issues.

6 CHIEF JUDGE BUMB: Yeah.

7 MR. HARKINS: We do think he is still competent to
8 state from his experience whether someone in the industry
9 evaluating it would view those products as being adulterated or
10 not adulterated, which is similar to the statements that
11 plaintiffs experts are being permitted to make in the opposite
12 direction.

13 CHIEF JUDGE BUMB: Okay. So assuming you can lay
14 that foundation, I think 25, 26 and 27, I mean they're factual.
15 I mean, if the FDA never declared the products to be
16 adulterated, then they didn't. But they did recall them.

17 So I don't know that it's significant. But I don't
18 see any reason why 25, 26 and 27 can't come in.

19 MR. STANOCH: Well, that was also part of the summary
20 judgment ruling from Judge Kugler where he termed this
21 "sophistry" for other experts. The whole point of defendants'
22 argument there is they never declared it, you need a formal
23 retrospective pronouncement of adulteration. As long as
24 they're not arguing that.

25 CHIEF JUDGE BUMB: They're not.

1 MR. STANOCH: Thank you.

2 CHIEF JUDGE BUMB: They won't.

3 MR. STANOCH: Thank you.

4 CHIEF JUDGE BUMB: Thirty-three is out.

5 Thirty-four is partly out. So let's see. The second
6 sentence -- the first sentence is out, and the second sentence
7 is in. I think it's -- I think the second sentence is fair
8 game. But the first sentence in 34 is out.

9 49, let's see, 49. I think 49 is out. I think
10 that's a jury question. I don't think that this expert should
11 be permitted to testify that it was reasonable for Teva to
12 expect the FDA would have done a risk assessment. I think
13 that's a jury question. I think that goes too close to opining
14 for the jury.

15 And then the only other modification, clearly any
16 reference to the class certification report is out. I think
17 that the parties know that. And then paragraph -- the only
18 other changes, I think paragraph 190 is out. Let me go to 190.

19 And then I think in other respects Judge Kugler's
20 Order stands.

21 190 is out. That's argument.

22 MR. STANOCH: Okay.

23 CHIEF JUDGE BUMB: Okay. So that's for that motion.

24 MR. STANOCH: The only other thing, and thank you,
25 Judge. I'll just say that the first time there was a chart

1 that he excluded, Judge Kugler, about his appendix at table --
2 it's pages 36 to 38.

3 CHIEF JUDGE BUMB: Yeah.

4 MR. STANOCH: Those are the exact same appendix
5 appears in the liability report. But otherwise, we accept the
6 rest of your ruling. I would just point out that it -- if the
7 appendix at pages 36, 38 of the old -- the wrong report was
8 excluded, that identical thing should be excluded as well.

9 CHIEF JUDGE BUMB: Yes. Yes. Yes. Yes. Yes.

10 MR. STANOCH: That's all.

11 CHIEF JUDGE BUMB: Yes. Okay. So for that motion;
12 yeah?

13 MR. STANOCH: Yes.

14 MR. HARKINS: Understood, Your Honor.

15 MR. STANOCH: Thank you, Judge.

16 CHIEF JUDGE BUMB: Okay. Now let's go to the 2591.
17 Let me get to my notes.

18 Okay. What was the issue with this one? Remind me.

19 MS. ROSE: Oh, sure, Your Honor. ZHP Defendants
20 filed a very limited motion with respect to the admissibility
21 of Dr. Ali Afnan, ZHP's regulatory expert. It's very limited
22 in scope. The Court excluded portions of only six paragraphs
23 of Dr. Afnan's 212-paragraph report. And our motion only
24 relates to three of those excluded paragraphs.

25 CHIEF JUDGE BUMB: Yeah. Tell me which ones.

1 MS. ROSE: Sure. It's paragraph 24, 69 --

2 CHIEF JUDGE BUMB: Wait. 124.

3 MS. ROSE: No, sorry. Just 24.

4 CHIEF JUDGE BUMB: Twenty-four. Because I read
5 through them and I'll tell you what I -- okay. Twenty-four.

6 MS. ROSE: 69.

7 CHIEF JUDGE BUMB: Okay.

8 MS. ROSE: And 138.

9 CHIEF JUDGE BUMB: Okay. Twenty-four is out. It's a
10 jury question.

11 Sixty-nine is fine. It stays.

12 And 138 you said? Yeah. Jury question. So it's
13 out.

14 MS. ROSE: And, Your Honor, can I just raise one of
15 the points in our motion?

16 CHIEF JUDGE BUMB: Yeah.

17 MS. ROSE: I appreciate your ruling.

18 CHIEF JUDGE BUMB: Okay. So one's in; two's out.

19 MS. ROSE: One's in; two's out.

20 So the basis of our motion is really an inequity.
21 It's, as you said earlier, a goose/gander issue, where if
22 paragraphs 24 and 138 which relate to Dr. Afnan's opinions as
23 to whether valsartan was biologically equivalent to the
24 reference listed drug Diovan and whether it was adulterated are
25 out as legal opinions, then the corresponding opinions from

1 plaintiffs' experts, Drs. Najafi and Plunkett, that offer the
2 opposite view, that it was adulterated, that valsartan was
3 adulterated --

4 CHIEF JUDGE BUMB: You didn't show me that, though,
5 did you? You didn't show me those reports and where they were,
6 right?

7 MS. ROSE: Oh, not yet. I'm happy to -- they're
8 discussed in our papers, but I'm happy to go through them with
9 you right now, if that's helpful.

10 CHIEF JUDGE BUMB: Do you have the reports?

11 MS. ROSE: I have the reports, and I have the
12 specific paragraphs that we referenced, specifically
13 referenced.

14 CHIEF JUDGE BUMB: How many paragraphs are there?

15 MS. ROSE: Sure. For Dr. Najafi, there's paragraph
16 4, paragraph 10, paragraph 29.

17 Oh, I'm so sorry. It's in pages. He does not have
18 paragraphs, so it's pages. Maybe it's best to just --

19 CHIEF JUDGE BUMB: Tell me the argument again.

20 MS. ROSE: So Dr. Afnan was excluded on -- now you've
21 limited it to paragraph 24 and 138 -- on the grounds that it's
22 a legal opinion; that he offers the opinion that valsartan was
23 not adulterated at the time of purchase and that it was
24 equivalent biologically to the reference-listed drug Diovan.
25 And if that's the case, Dr. Afnan's opinions are offered in

1 direct response to plaintiffs' expert's opinions saying the
2 opposite. Plaintiffs' experts are saying valsartan was
3 adulterated at the time of sale, use it under the same
4 regulatory framework, referencing the exact same regulations.

5 So if Dr. Afnan is offering a legal opinion in saying
6 that the drug was not adulterated at the time of sale,
7 plaintiffs' expert's opinions that the drug was adulterated at
8 the time of sale would equally be a legal opinion.

9 CHIEF JUDGE BUMB: Who has the competency to say
10 whether or not a drug is bioequivalent or not? Isn't that
11 within the sole realm of the FDA?

12 MS. ROSE: And that is Dr. Afnan's opinion actually.
13 Dr. Afnan's opinion is that it is the FDA who determines
14 adulteration and who determines bioequivalence.

15 CHIEF JUDGE BUMB: Right. And that would be fine for
16 him to say to the jury, which he will. That's in his report,
17 right?

18 MS. ROSE: Yes.

19 CHIEF JUDGE BUMB: Okay.

20 MS. ROSE: And he explains --

21 CHIEF JUDGE BUMB: Yes.

22 MS. ROSE: Sorry, Your Honor.

23 CHIEF JUDGE BUMB: So if it's the FDA that has that
24 competency to make that determination, how does this expert
25 have that competency?

1 MS. ROSE: So what Dr. Afnan's actually explaining is
2 that it is within the FDA's determination as to whether a drug
3 is adulterated.

4 CHIEF JUDGE BUMB: Yeah.

5 MS. ROSE: So plaintiffs' expert saying that in 2015
6 valsartan was adulterated, when the FDA had not deemed it
7 adulterated at that point, that that is -- that it's an
8 illogical opinion because it's the FDA that deems a drug
9 adulterated. And in 2015, the FDA looked at the API
10 manufacturing process, looked at valsartan, looked at all of
11 the information that ZHP had and said the drug was equivalent
12 to Diovan and it could be sold and it was not adulterated. It
13 approved the ANDA for that drug.

14 It wasn't until late 2018, after the recall, that the
15 FDA determined that the drug was adulterated.

16 CHIEF JUDGE BUMB: Right.

17 MS. ROSE: And at that point it could not be sold.

18 CHIEF JUDGE BUMB: Right.

19 MS. ROSE: So Dr. Afnan is simply explaining it is
20 the FDA who decides adulteration. And plaintiffs' experts
21 can't in retrospect decide the drug was adulterated at all
22 times.

23 CHIEF JUDGE BUMB: That sounds right. What?

24 MR. NIGH: Your Honor, these are two different
25 issues. They're not an equivalency. So what you've just heard

1 is the thrust of the defendants' argument; that the FDA didn't
2 declare or find that these were adulterated until some time
3 after 2018.

4 CHIEF JUDGE BUMB: Right.

5 MR. NIGH: The FDA's finding that "products" to be
6 adulterated. And the product is manufactured the same way
7 dating all the way back to 2015. So what our expert does is
8 opining on the timing of what that declaration means. Because
9 they want to say that declaration means, oh, it's just -- it's
10 not adulterated until the FDA comes out and says adulterated.
11 That's not right.

12 When the FDA is making that finding --

13 CHIEF JUDGE BUMB: Can you try this again, please.

14 MR. NIGH: Yes. Go ahead.

15 MR. SLATER: Can I just take a step back for a
16 second?

17 Number one, the entire premise of the motion is false
18 in the sense of we're not comparing apples to apples.

19 CHIEF JUDGE BUMB: Well, that's why I'm trying to get
20 to the bottom of it. Because if we're not comparing apples to
21 apples, that's what I need to understand.

22 MR. SLATER: Right.

23 CHIEF JUDGE BUMB: The argument has been made by the
24 defendants that somehow Judge Kugler -- which, parenthetically,
25 I thought was a little caustic and unnecessary -- that Judge

1 Kugler was being unfair to the defendants and favoring the
2 plaintiffs.

3 MR. SLATER: Right.

4 CHIEF JUDGE BUMB: If we're not comparing apples and
5 apples, then I need to know that. And I'm trying to understand
6 it.

7 When I went through and I read the Anderson report, I
8 ruled on the three paragraphs that I did. But are you telling
9 me that that's not the case; that I'm precluding Dr. Afnan --
10 or no, Dr. Anderson from saying that the drugs were not
11 adulterated, but I'm allowing the plaintiffs to say that they
12 were adulterated?

13 MR. SLATER: No. You had it right, Judge. It's
14 Dr. Afnan. I know it's a lot of names.

15 CHIEF JUDGE BUMB: Oh, Dr. Afnan, I just talked
16 about, yeah.

17 MR. SLATER: Yeah. There's As.

18 CHIEF JUDGE BUMB: Yeah. I have my chart of who's
19 who here. I'm going to put it back up. Okay.

20 MR. SLATER: This is one of -- there's a few reasons
21 why it's not apples to apples. But the most important is,
22 Dr. Afnan is an expert in cGMP.

23 CHIEF JUDGE BUMB: Okay. Yes. Right.

24 MR. SLATER: The defense is now saying, well, if he
25 can't give these opinions, why are you letting the plaintiffs'

1 experts, Dr. Najafi and Dr. Plunkett and Dr. Hecht, who
2 Dr. Afnan was criticizing their opinions, they're in different
3 fields.

4 CHIEF JUDGE BUMB: Yeah. Okay.

5 MR. SLATER: Our counterpart expert, Dr. Binge, was
6 also significantly cut down by Judge Kugler. So the matchup
7 expert was cut down drastically by the rulings.

8 CHIEF JUDGE BUMB: Oh.

9 MR. SLATER: Dr. Najafi is a chemistry expert who is
10 also permitted to give regulatory opinions based on his
11 regulatory background in the *Daubert* motions. Dr. Plunkett is
12 a regulatory expert and a toxicologist. And Dr. Hecht is a
13 chemist. Dr. Afnan is not an expert in any of those fields in
14 this case.

15 So what Judge Kugler was doing was analyzing
16 qualifications. He was analyzing methodology. And ultimately
17 what I think happened was, whereas our experts went through,
18 for example, with adulteration where they're qualified, take
19 Dr. Plunkett, for example, to say, okay, this is the standard
20 for what adulteration is, now let me tell you what happened,
21 let me tell you what the issues were with the drug and you put
22 it together. We have Dr. Afnan who doesn't have the
23 qualifications --

24 CHIEF JUDGE BUMB: Right.

25 MR. SLATER: -- and didn't follow that methodology

1 coming in and giving a legal conclusion, which I equate to a
2 net opinion to say it wasn't adulterated, and he relies on --
3 obviously there's an MIL on this and it's an issue that kind of
4 didn't come out --

5 CHIEF JUDGE BUMB: So he's just not qualified. He's
6 not qualified.

7 MR. SLATER: He --

8 CHIEF JUDGE BUMB: He's a 70 --

9 MR. SLATER: Right. He's not the right expert. So
10 he's drawing legal conclusions that are net opinions. And the
11 first one is a really good example where he comes up with what
12 Judge Kugler said was sophistry in the context of Dr. Anderson
13 where Anderson said you can't give a retrospective analysis to
14 say a drug was adulterated. You need the FDA to say it's
15 adulterated, and it only becomes adulterated from that point
16 forward. Judge Kugler rejected that. That's what Dr. Afnan's
17 opinion in paragraph 24 is, where he's saying it can't be ruled
18 adulterated because it's too late because it's after the fact,
19 which is obviously not the law. And obviously there's no basis
20 for it. So that is a legal conclusion. It also has no basis
21 and it's net opinion.

22 So I'm giving that example because it was the first
23 one on the list. So you're talking about experts who are
24 qualified in different fields.

25 And I'll take it a step further, because counsel took

1 this argument with Your Honor about the FDA is the only entity
2 that can decide whether a drug was adulterated or not. The FDA
3 ruled that the API manufactured by ZHP was adulterated due to
4 cGMP violations. That was the FDA's decision.

5 The FDA didn't say it's only adulterated due to cGMP
6 violations as of today, because it was after the drug was off
7 the market. They're saying for the entire time it was sold,
8 there were these systemic cGMP violations and it was
9 adulterated.

10 So if we take the defendants' argument to its logical
11 conclusion, which I think we should, if they're right that the
12 FDA makes that decision, they did make that decision, and they
13 shouldn't be allowed to relitigate at this trial through their
14 experts decisions the FDA made, because that's what they want
15 to do. And I know this is starting to spill into a few other
16 motions, but there's a systemic theme here where the defense
17 wants to relitigate FDA findings.

18 That API was made in violation of cGMPs. It was
19 adulterated. It led to one letter that documented an import
20 ban where ZHP couldn't sell into the United States for three or
21 four years. That's official action with official consequences.

22 So if they're right, then that API was adulterated.
23 Any pill that it was in was adulterated by definition, because
24 how could a pill containing the adulterated API not be
25 adulterated? So, therefore, we prevail on those issues,

1 because the FDA decided it.

2 The alternative is we're going to try the case and
3 Dr. Afnan, if permitted, or some other experts for the defense
4 are going to say, no, the FDA was wrong. We didn't violate
5 cGMPs. And, no, this wasn't adulterated, which I don't think
6 that should be permitted. The FDA made final decisions. I
7 don't think it's for a jury to say, well, the FDA was wrong
8 about that. This led to worldwide recalls and import bans. So
9 I don't --

10 CHIEF JUDGE BUMB: The issue is, is who's qualified
11 to render an opinion as to whether the failure to have proper
12 cGMPs in place led to a drug that was adulterated, right?

13 MR. SLATER: That's -- that's -- in terms of what
14 Dr. Afnan is trying to get at?

15 CHIEF JUDGE BUMB: Yes.

16 MR. SLATER: That's part of what he's saying, yes,
17 yes. That's a big part of it.

18 MS. ROSE: Your Honor.

19 CHIEF JUDGE BUMB: And he's permitted to say that
20 they followed procedures and therefore they weren't
21 adulterated.

22 MR. SLATER: I don't think so. Because as our motion
23 pointed out, and I think it may have just been a process issue
24 because there were so many *Daubert* motions, Dr. Xue is the
25 chemistry expert for ZHP.

1 CHIEF JUDGE BUMB: Okay.

2 MR. SLATER: He's been precluded from basically doing
3 anything other than explaining the manufacturing process that
4 was used. He can't give any substantive opinions defending
5 ZHP. His opinions were eviscerated on the *Daubert* motion.

6 CHIEF JUDGE BUMB: Okay.

7 MR. SLATER: Dr. Afnan in his report and his
8 deposition and even defense counsel who defended the deposition
9 made it clear, he's not an expert in chemistry in this case.
10 He has a Ph.D. in chemistry, but he said it and counsel said
11 it, he was not proffered as an expert in chemistry.

12 CHIEF JUDGE BUMB: Right.

13 MR. SLATER: So he relied on Dr. Xue for all the
14 chemistry-related opinions, including the only way you could
15 say there was or was not a cGMP violation is if you are relying
16 on somebody whose opinions are coming in where you are
17 independently qualified to give the opinions that whether or
18 not there was knowledge about these risks, how did you
19 understand whether or not there was a risk of NDMA formation,
20 et cetera. Those are all chemistry questions.

21 And, for example, nobody in the chemistry world knew
22 about this. Again, a chemistry opinion. So it undercuts any
23 effort by Dr. Afnan to say they didn't violate cGMPs because it
24 relies on chemistry expertise. He relied on an expert who's
25 been precluded. So all of his opinions go out. Frankly, we

1 think all of his opinions are out other than maybe giving some
2 background like Dr. Xue without giving opinions about whether
3 or not something was violated. And that's the import of our
4 cross-motion.

5 Judge Kugler did not address that question in his
6 decision. I'm guessing, perhaps, with all the motions, maybe
7 Xue had been decided first and then Afnan came, and it's asking
8 a lot then to come back and say now how do we apply Xue and
9 Afnan or whatever. I have no idea what happened. And I'm
10 certainly not casting aspersions, but that issue was not
11 addressed. So that's why we, when we moved to amend the order
12 as to Dr. Afnan, cross-moved on Dr. Afnan because we felt there
13 was this huge gap that had been overlooked because Dr. Afnan
14 was relying almost entirely on Dr. Xue for his entire report.
15 And Dr. Xue's opinions were precluded. And obviously we have a
16 motion in limine on that issue, too, the same issue. An expert
17 can't rely on an opinion that's been precluded by the Court.

18 MS. ROSE: Your Honor, can I address? There was a
19 lot that --

20 CHIEF JUDGE BUMB: I don't know. I'm getting kind of
21 confused.

22 MS. ROSE: There was a lot that was going on there.
23 So I'll try to simplify. I'll take it back.

24 MR. SLATER: I know you're here for me.

25 MS. ROSE: Yeah. I'm here to simplify.

1 Okay. So there are two motions with respect to
2 Dr. Afnan. Our motion to clarify, which we were addressing.
3 Adam went into his separate cross-motion. I really think you
4 need to address them differently or separately or at least one
5 at a time. I'm happy to do both. So I'll first just respond
6 to what Adam said with respect to Dr. Afnan's opinions and
7 whether or not they're legal opinions.

8 So Adam's point here that he first made was that this
9 was a qualifications order. That's not what doctor -- sorry,
10 that's not what Judge Kugler's Order is. Judge Kugler's Order
11 was very clear that this was about whether or not it was a
12 legal opinion, and it was not about qualifications.

13 I will speak briefly about qualifications.

14 CHIEF JUDGE BUMB: Well, when I read through the
15 report, it does not seem that he is qualified to render an
16 opinion as to whether they were adulterated because he's not a
17 chemist. He didn't have the knowledge as to what was
18 bioequivalent to the other drug. He was an expert in the area
19 of what the practices were, the GMPs were, right?

20 MS. ROSE: Can I speak to that for one second?

21 CHIEF JUDGE BUMB: Okay.

22 MS. ROSE: So Dr. Afnan has a Ph.D. in chemistry. He
23 in addition -- and plaintiffs like to limit him to just a cGMP
24 expert. But he is an FDA expert. He worked at the FDA. He's
25 worked --

1 CHIEF JUDGE BUMB: Right, as to the cGMPs, right?

2 MS. ROSE: He goes -- but he goes beyond cGMPs to
3 discuss FDA regulations, FDA testing, FDA --

4 CHIEF JUDGE BUMB: Are you folks both arguing over
5 Dr. Afnan? You both have --

6 MR. SLATER: Yes.

7 CHIEF JUDGE BUMB: Okay. We're going to bring him
8 in. We'll do a *Daubert* hearing. We'll do a *Daubert*.

9 MS. ROSE: Okay.

10 CHIEF JUDGE BUMB: I can't rule in a vacuum as to --
11 we'll do a *Daubert* on that one. That will be easier for me to
12 rule on.

13 Okay. Should we start with -- I have two left. 2649
14 and 2710, right? Yes. Right?

15 MS. ALLON: 2648, Your Honor?

16 CHIEF JUDGE BUMB: 2648 I ruled on, didn't I?

17 MS. ALLON: No. 2648 is the plaintiffs' motions in
18 limine.

19 CHIEF JUDGE BUMB: And 2649 are the defendants?

20 MS. ALLON: Yes.

21 CHIEF JUDGE BUMB: And 2710, did I rule on that?

22 Oh, this is the -- is this the sanctions motion,
23 2710?

24 No. I've already ruled. That's the champerty. I
25 ruled on that one.

1 Okay. So I think we're left with the motions in
2 limine for both sides, and then we're left with Judge
3 Vanaskie's order relating to Chen, right?

4 MS. LOCKARD: Your Honor, there were also motions in
5 the parties' trial briefs, which were 2682 and 2681.

6 CHIEF JUDGE BUMB: What are they? Just tell me what
7 they are, please.

8 MS. LOCKARD: There are a number of motions in the
9 parties' trial briefs on various issues.

10 CHIEF JUDGE BUMB: Oh, in the trial briefs?

11 MS. LOCKARD: Correct.

12 CHIEF JUDGE BUMB: I have to look at this. Because
13 if you folks don't have to quarrel about these things, you're
14 not going to.

15 Go to the trial briefs. What page?

16 MS. LOCKARD: Those were 2682 and 2681.

17 CHIEF JUDGE BUMB: Oh, I know. Some of these I
18 just -- I was like really? Really?

19 (Laughter.)

20 CHIEF JUDGE BUMB: Come on.

21 MS. LOCKARD: I'm not suggesting this takes priority
22 over anything. I just wanted to --

23 CHIEF JUDGE BUMB: No; I know. But, by golly, I
24 took -- you know, I have read through -- look, I mean, I'm
25 highlighting this stuff and I'm writing notes and I'm like

1 really?

2 MS. LOCKARD: There may be many you can rule based on
3 the brief, but it's just pending.

4 CHIEF JUDGE BUMB: All right. I'll try to get to
5 them.

6 Here's one of my notes. "This is so obvious."

7 I mean, good time for a lunch break. I think it's
8 past lunchtime. All right. Let's take a break. Let's come
9 back at 2:00, okay?

10 MS. DAVIDSON: Your Honor, before we take a lunch
11 break, can I ask a procedural question?

12 CHIEF JUDGE BUMB: Yes.

13 MS. DAVIDSON: In light of the fact that the
14 sanctions order reissued yesterday, I assumed Your Honor would
15 want us to submit briefing on that because it sort of
16 supersedes --

17 CHIEF JUDGE BUMB: Yeah, I did. But I want it really
18 short, because I really want to get to it.

19 Look, I think -- I'm just going to tell you. I mean,
20 I'll deal with what Judge Vanaskie ruled yesterday. I haven't
21 looked at it to see. But, I mean, I think he got it right. So
22 we can talk about it. But I'm not going to deprive you of the
23 opportunity to brief it. But I just don't see that we should
24 be delaying this. But I do have questions about it, though.
25 Because I have questions for ZHP. And the big question I have

1 is, well, what have you done about it lately?

2 You know, you folks want to spend time about telling
3 me how Judge Vanaskie got it wrong, but then what have you done
4 about it lately? What have you done to secure Chen here, or
5 secure his deposition? I don't know. Probably nothing. So
6 what do you want me to do? That's how I feel about it.

7 All right. Let's come back at 2:00. Okay.

8 THE COURTROOM DEPUTY: All rise.

9 (Recess was taken at 1:14 p.m. until 1:59 p.m.)

10 THE COURTROOM DEPUTY: All rise.

11 CHIEF JUDGE BUMB: Okay. Case dismissed?

12 (Laughter.)

13 CHIEF JUDGE BUMB: You can all have a seat. Thank
14 you.

15 Okay. Everybody here?

16 So over lunch, did you folks work out any of these
17 motions?

18 (No response.)

19 CHIEF JUDGE BUMB: 2648, plaintiffs' motions in
20 limine. All right. There's quite a few of them. So let's
21 plod through them.

22 Okay. "Defendants cannot assert that it is not
23 appropriate to perform a retrospective analysis of their
24 conduct or the consequences, including, for example, the
25 resulting adulteration of the contaminated API and VCDs."

1 Oh, this is going to be -- some of this is just --
2 okay. You get two sentences and then you get two sentences and
3 then I'll rule.

4 What is this about?

5 MR. SLATER: In the depositions of the -- many of the
6 witnesses and in the expert reports and expert testimony from
7 defense witnesses, they said that you cannot say
8 retrospectively that the pills, the API, the finished dose, was
9 adulterated because it only -- you can't say it
10 retrospectively. It's only a prospective opinion that you can
11 give. And that -- obviously that's, again, Judge Kugler
12 rejected that. And it makes no sense, because the FDA
13 evaluates this after the fact and says the pills were
14 adulterated. They were off the market by the point the FDA
15 said they were adulterated. So they were adulterated while
16 they were sold. And the defense should not be allowed to tell
17 the jury you can't retrospectively decide. But that's what we
18 do at a trial. We retrospectively decide what happened.

19 CHIEF JUDGE BUMB: Yeah. Uh-huh.

20 MR. HARKINS: Your Honor, I do think this touches on
21 something related to the argument over Dr. Afnan prior to the
22 break, which is defendants' position is that the FDA is the
23 only entity that can say a product is or is not adulterated.
24 The limitation that's cited in the plaintiffs' motion on the
25 testimony of defense expert Dr. Roger Williams relates to not

1 just whether that was adulterated but then trying to look
2 retrospectively back at it.

3 And we understand Judge Kugler's Order as precluding
4 Dr. Williams from opining on the ultimate issue of whether the
5 product was adulterated. As stated before the break, we don't
6 think any party should be permitted to step into the shoes of
7 the FDA and have their witness say that their product was or
8 was not adulterated.

9 CHIEF JUDGE BUMB: Yeah. Are we just mincing words?
10 I mean, are we just being a little too technical here? It is
11 only the FDA that can declare a drug is adulterated.

12 MR. HARKINS: Agree.

13 CHIEF JUDGE BUMB: But there are certainly those who
14 are competent in the industry to be able to look at a drug and
15 to determine whether or not it is impure, for example.

16 Do you agree with that statement?

17 MR. HARKINS: We do, Your Honor.

18 CHIEF JUDGE BUMB: Okay. So therefore?

19 MR. HARKINS: Defendants' experts will present
20 testimony -- and it's a little confusing to determine exactly
21 what plaintiffs are trying to get at with this motion, how much
22 retrospective analysis they're trying to preclude us from
23 presenting. But we are certainly going to introduce the
24 evidence of the existing knowledge in the industry prior to the
25 recall.

1 CHIEF JUDGE BUMB: Okay.

2 MR. HARKINS: What steps were taken by each of the
3 defendants to manufacture, test, and keep their product in
4 compliance with the then existing specifications.

5 CHIEF JUDGE BUMB: So far so good.

6 MR. HARKINS: And we are going to say that based on
7 all of those steps, all the conduct that we'll demonstrate
8 through both our corporate witnesses and expert testimony, that
9 the product at the time of sale was not adulterated. That is
10 the argument that we will make to the jury.

11 We understand that plaintiffs are going to make a
12 different argument to the jury, but we can't be prevented from
13 pointing to the fact that regulations that only postdate the
14 recall, standards that were not in place at the time the drug
15 was manufactured and sold, were in existence, were operative.
16 We're going to point to them and then at the end we will make
17 the argument regarding adulteration.

18 CHIEF JUDGE BUMB: So let me make sure that we're
19 not -- that we're not sort of cross-talking here.

20 The FDA is the agency that declares a drug
21 adulterated, right?

22 MR. HARKINS: That's correct, Your Honor.

23 CHIEF JUDGE BUMB: Okay. We agree with that so far?

24 MR. SLATER: Yes. That's within the FDA's
25 jurisdiction.

1 CHIEF JUDGE BUMB: Okay. That does not mean,
2 however -- let me state it differently. Anyone who is
3 competent, a chemist, for example, is competent to determine
4 whether or not there is an impure or that there's a trace of
5 a -- let's just say there's a trace of a carcinogen in the drug
6 and therefore it is not pure, and therefore it would be
7 deemed -- it could be deemed adulterated or it would be. It is
8 adulterated. We agree on that sentence?

9 MR. SLATER: Oh, yeah.

10 CHIEF JUDGE BUMB: Do you agree on that sentence?

11 MR. HARKINS: We understand that's the argument the
12 plaintiffs are going to make.

13 CHIEF JUDGE BUMB: Why do you disagree with it, then?

14 MR. HARKINS: Because there is no evidence in this
15 case prior to the announcement of the recall and then the
16 subsequent warning letter issued by the FDA of any
17 determination by that agency that this product was adulterated.

18 CHIEF JUDGE BUMB: Okay. So this is what I'm saying:
19 They're not quarreling with that. I think we have to be
20 careful how we're framing the issue.

21 They are not quarreling with you that prior to the
22 determination by the FDA that the drug was adulterated, there
23 was no determination by the FDA the drug was adulterated.
24 They're not quarreling with that.

25 What they are quarreling with, though, is that there

1 is evidence in the record that procedures weren't followed;
2 that there were traces of the carcinogen in it and therefore
3 the drug was adulterated. Wasn't deemed adulterated by the
4 FDA. But it was adulterated. That's fair game.

5 MR. HARKINS: And, Your Honor --

6 CHIEF JUDGE BUMB: There's two different issues.

7 MR. HARKINS: I agree.

8 CHIEF JUDGE BUMB: Yeah. Okay.

9 MR. HARKINS: I think that's a core question of fact
10 that both parties are going to present competing evidence on.
11 We understand that that is the statement the plaintiffs are
12 going to make and try and introduce evidence as to. And we are
13 going to introduce evidence of all of the steps in compliance
14 with then existing regulations prior to the discovery of the
15 nitrosamine impurity to make the argument that that product was
16 not adulterated at the time of sale.

17 CHIEF JUDGE BUMB: So it seems to me you both are
18 agreeing on this motion. Where's the disconnect?

19 MR. SLATER: One clarification. The FDA did actually
20 make the finding that the ZHP API was adulterated. It's in the
21 warning letter as an official finding.

22 CHIEF JUDGE BUMB: Yeah.

23 MR. SLATER: And they based it on the fact that they
24 found that ZHP violated cGMPs.

25 CHIEF JUDGE BUMB: Right.

1 MR. HARKINS: Yeah.

2 MR. SLATER: I thought Your Honor had said that there
3 had been no finding of adulteration. I just wanted to make
4 that clear.

5 But our motion was based on the defense witnesses
6 saying you can't do a look back and declare -- and say in this
7 trial that something was adulterated; that the pill was
8 adulterated. That was the point, was that we don't believe
9 that any defense witness or defense expert should say it's
10 inappropriate to look back and evaluate whether the drug was
11 adulterated during the time period it was on the market. Their
12 argument was you can't look back and do that. That's --
13 there's -- I can tell you, there's a lot of ZHP witnesses who
14 said it throughout their depositions, you can't retrospectively
15 evaluate it and say it was adulterated. It has to be a current
16 decision that you make. So that was the import of this motion.
17 And I'll come back to what we talked about earlier.

18 The defense keeps saying: Only the FDA can decide if
19 the drug was adulterated. If they really mean that, the FDA
20 deemed the drug adulterated. That's an official finding the
21 FDA made based on the violations of current good manufacturing
22 practices. So if only the FDA can make that determination, as
23 a matter of law, the FDA ruled that it was adulterated and that
24 ZHP violated cGMPs. So that should be decided as a matter of
25 law. Because if only the FDA can make that ruling or make that

1 finding, the FDA did make that finding.

2 If they want to litigate it, they can litigate it.
3 But they can't say you can't look back at it because it's
4 inconsistent.

5 MR. HARKINS: Your Honor, the Court denied this
6 motion in the summary judgment ruling. The question of whether
7 or not the product was adulterated --

8 CHIEF JUDGE BUMB: I'm trying to understand what the
9 motion is.

10 MR. HARKINS: A little bit as well, Your Honor.

11 The only two points I guess I would make to clarify,
12 one, there is no statement from the FDA as to Teva's
13 finished-dose product anywhere. Not in the warning letter the
14 plaintiffs reference, not in any communications with Teva, not
15 in any public statement from the FDA stating that that product
16 was adulterated. There is no statement or determination from
17 the FDA that Teva's product was not in compliance with cGMPs in
18 connection with the recall, the warning letter.

19 THE COURT: And that's fine. You'll make that
20 argument to the jury. But that doesn't preclude the plaintiffs
21 from showing otherwise; that their experts will say that we
22 looked at the cGMPs and we looked at what was followed, it
23 wasn't followed, and we found traces of nitrosamine, et cetera.

24 MR. HARKINS: And, Your Honor, this is -- we have not
25 moved to keep plaintiffs from introducing that evidence.

1 They're moving to keep us from introducing evidence that we did
2 comply with cGMP and that our product was adulterated.

3 MR. SLATER: That's not what the motion is.

4 THE COURT: Okay. Let's --

5 MR. SLATER: We're arguing over a motion that wasn't
6 filed.

7 CHIEF JUDGE BUMB: Okay. Let's start over.

8 MR. SLATER: On this motion. That was a different
9 motion. It was a different issue. But --

10 CHIEF JUDGE BUMB: Tell me the motion.

11 MR. SLATER: All this motion was, was to address
12 defense witnesses and defense experts saying you can't say that
13 the drug was adulterated in the past tense.

14 CHIEF JUDGE BUMB: You can.

15 MR. SLATER: That's -- full stop, that's the motion.

16 CHIEF JUDGE BUMB: I don't think they're quarreling
17 with that. I think what they're saying is, you can't say that
18 the FDA declared it adulterated before the FDA declared it
19 adulterated.

20 MR. SLATER: I'm --

21 CHIEF JUDGE BUMB: I don't know. I'm just not
22 following the argument.

23 MR. SLATER: I'm not sure what -- my argument was
24 literally what I said, full stop, that was literally the only
25 part -- that's what this motion was.

1 CHIEF JUDGE BUMB: Okay. Ask the question. Judge,
2 are we permitted to? Ask the question.

3 MR. SLATER: Is the defense permitted to put up
4 witnesses who will tell the jury it is not appropriate and you
5 cannot find that a drug was adulterated by looking back at what
6 had happened and saying that drug was adulterated?

7 CHIEF JUDGE BUMB: What's the answer?

8 MR. HARKINS: That plaintiffs' witnesses are going to
9 state that it is appropriate to do that. Our experts,
10 similarly qualified, are going to say it is not appropriate.

11 CHIEF JUDGE BUMB: And why not?

12 MR. HARKINS: Because the determination is made by
13 the FDA at the time. It is not, and it could be, under any
14 other enforcement mechanism that the FDA did not choose to use
15 here, they could issue a finding, they could issue an
16 injunction, they could take additional steps to demonstrate
17 that they view there to be prior problems with the product.
18 They didn't do that here.

19 They also did not make that finding with respect to
20 all product in this case, specifically none of the
21 finished-dose product manufactured by Teva.

22 CHIEF JUDGE BUMB: You are putting far too much power
23 in the hands of the FDA.

24 There is no reason why a court or any other expert
25 could opine that the drug was adulterated. Simply because the

1 FDA, let's just say, might be asleep at the switch doesn't mean
2 the drug wasn't adulterated.

3 MR. HARKINS: Your Honor, all we're asking for is for
4 the ability for our experts to respond to the question -- what
5 I understand the motion to be is the plaintiffs would like to
6 preclude our experts from saying that it is inappropriate to --
7 that it's inappropriate to apply that adulteration
8 determination retroactively. Their experts are going to argue
9 that it is appropriate to do so.

10 CHIEF JUDGE BUMB: That's why I say, I just -- I
11 think we're confusing -- I think what the defendants are saying
12 is that it is inappropriate for the plaintiffs to stand before
13 the jury and argue to the jury that the FDA declared the drug
14 adulterated before it declared the drug adulterated. That's
15 what I'm hearing you say.

16 MS. DAVIDSON: Your Honor, can I say something?

17 CHIEF JUDGE BUMB: Well, can he answer my question?

18 MR. HARKINS: Sure. Your Honor, that is not what we
19 are concerned about having precluded here.

20 CHIEF JUDGE BUMB: What? Try it again.

21 MR. HARKINS: We understand from this motion that
22 plaintiffs want to preclude our experts from saying it is
23 inappropriate, based on the 2018 adulteration determination by
24 the FDA, to say that all product manufactured prior using the
25 same process is necessarily adulterated. That is what our

1 experts want to say, which is a direct response to plaintiffs'
2 experts who are going to claim that that is appropriate to do.
3 They are going to claim, we understand it from their deposition
4 testimony --

5 CHIEF JUDGE BUMB: Okay.

6 MR. HARKINS: -- that that determination can and
7 should be applied retroactively. We can respond to that with
8 our experts.

9 CHIEF JUDGE BUMB: It's inappropriate or it's wrong,
10 you don't agree with it? I just -- I want to make sure that
11 I'm not getting --

12 MR. HARKINS: Sorry. Our experts disagree that that
13 is a correct application of the FDA's determination, of the
14 FDA's adulteration determination. I'm sorry if I'm not
15 answering Your Honor's question.

16 MS. DAVIDSON: Your Honor, may I just, two minutes,
17 not even? I'll stick to the two sentences starting now.

18 So if you look at page 32 of the Court's Summary
19 Judgment Order, the Court makes very clear that whether ZHP's
20 API was adulterated is the central fact in dispute in this
21 matter. And the Court goes on to say: It is important to note
22 that ZHP and the finished-dose manufacturers vigorously argue
23 that before November 28, 2018 the FDA never declared the API
24 adulterated.

25 The Court recognized this issue is a core, central

1 fact in dispute. All we're asking is that you deny the motion
2 and allow our experts to give their opinions. This isn't a
3 motion by us to keep anything out. This is a motion by
4 plaintiffs to bar our experts from expressing their opinions as
5 to why the product was not adulterated before the date of the
6 letter, November 28, 2018.

7 CHIEF JUDGE BUMB: And the defendants can argue that
8 the FDA never declared it adulterated, because they didn't. I
9 don't think that's in dispute. But that doesn't prevent the
10 plaintiff from coming forward and showing that it was.

11 MR. HARKINS: And, Your Honor, we're not seeking to
12 prevent the plaintiffs from doing that.

13 THE COURT: Okay.

14 MR. SLATER: One second, Your Honor.

15 MS. DAVIDSON: We haven't moved to exclude anything
16 on this topic.

17 MR. HONIK: Your Honor, at the risk of further
18 complicating things, if I may, Judge Kugler weighed in on this
19 in a very specific way on this very narrow issue. At ECF 2581
20 the Court wrote: "Williams" -- the expert -- "states that the
21 contaminated VCDs could not have been adulterated before the
22 FDA became aware of the contamination in the summer of 2018,"
23 full stop.

24 Judge Kugler then wrote: "This is sophistry, which
25 attempts to avoid a retrospective characterization of Teva's

1 finished-dose products as adulterated from the start of the
2 nitrosamine contamination." There's a ruling on this,
3 respectfully.

4 CHIEF JUDGE BUMB: Can you --

5 MR. HONIK: And the rules --

6 THE COURT: Can you just pause for a second so I can
7 read what you just said.

8 (Pause.)

9 MR. HONIK: And I believe, Your Honor, the essential
10 point is this. I'll try to distill it as succinctly as I think
11 I can.

12 Let's say the FDA determined adulteration on July 18,
13 2018. To therefore say that the drug was not adulterated on
14 July 17th is absurd.

15 CHIEF JUDGE BUMB: They're not saying that. They're
16 not disputing that.

17 They are saying that you can go ahead and present
18 evidence, if you want, and you will, that the plaintiff is
19 going to produce that it was adulterated before it was declared
20 adulterated. They're not preventing you from making that
21 argument and presenting that evidence.

22 MR. HONIK: But the nub of the motion that we brought
23 is they're turning that on its head and saying that it's
24 literally impossible to have an adulteration before the date on
25 which the FDA made the pronouncement.

1 CHIEF JUDGE BUMB: No. I don't -- can you read that
2 again?

3 (Court reporter clarification.)

4 MR. HONIK: My apologies. The entire --

5 CHIEF JUDGE BUMB: If you -- have you marked up your
6 document?

7 MR. HONIK: It is marked up. It's actually in our
8 papers. It's on page 1.

9 CHIEF JUDGE BUMB: Go ahead and read it to me again,
10 please.

11 MR. HONIK: Sure. So, again, this is found at ECF
12 2581, in which the Court wrote, and I quote: "Williams states
13 that the contaminated VCDs could not have been adulterated
14 before the FDA became aware of the contamination in the summer
15 of 2018. This is sophistry, which attempts to avoid a
16 retrospective characterization of Teva's finished-dose products
17 as adulterated from the start of the nitrosamine
18 contamination."

19 CHIEF JUDGE BUMB: Okay.

20 MR. HONIK: And I think the essential point is simply
21 that the date that the contamination is found, for the
22 defendants to therefore say you can't go back and say anything
23 about the adulterated status of the drug before the date on
24 which the pronouncement occurs is nonsensical.

25 CHIEF JUDGE BUMB: I don't think they're saying that.

1 Are you saying that?

2 MR. HARKINS: That is not what we are saying, Your
3 Honor.

4 CHIEF JUDGE BUMB: No, they're not saying that.

5 MR. HARKINS: And to contextualize the quote with
6 regard to Dr. Williams, this, along with a number of other
7 opinions in his report, was limited. And we interpret that as
8 the Court limiting his ability to opine on what is really an
9 ultimate issue. Whether the product was adulterated is one of
10 the central issues in the case. He should not as an expert, as
11 we understand the Court's rulings, be able to make that final
12 step and describe to the jury the conclusion; that it was not
13 necessarily adulterated.

14 CHIEF JUDGE BUMB: Okay. I'm getting just somewhat
15 lost. But here's what I'm going to say: He cannot opine that
16 the drug was not adulterated until the FDA declared it was
17 adulterated. He can't opine. That's not the right state of
18 the law. It's not what the law is.

19 He can say -- he can say that only the FDA can
20 declare it adulterated. But just simply because the FDA
21 declared it adulterated when it did does not necessarily mean
22 that it wasn't adulterated before.

23 MR. HARKINS: I agree, Your Honor. I just see that
24 the way that this is being positioned, it occurs that
25 plaintiffs are going to make the opposite argument, and we're

1 not going to be able to rebut that with our own expert
2 saying --

3 CHIEF JUDGE BUMB: What's the opposite argument they
4 would make? They want to be able to make the argument that
5 just simply because the FDA hadn't declared it adulterated does
6 not mean that it wasn't adulterated before they declared it
7 adulterated.

8 MR. HARKINS: And if I'm misunderstanding plaintiffs'
9 argument, I apologize. But I understand it to be that they
10 want to say the product was adulterated for the entire time
11 period prior to the adulteration determination.

12 CHIEF JUDGE BUMB: Not wasn't declared adulterated by
13 the FDA, but they can -- their experts can opine that it was,
14 in fact, adulterated for the reasons the experts will so say.

15 Are we in agreement now?

16 MR. SLATER: We're in agreement that our experts are
17 going to say that. I want to just make -- because Your Honor
18 is getting now obviously the feel for the case, and I think
19 it's important to point out what's happening here.

20 ZHP is here as the API manufacturer.

21 CHIEF JUDGE BUMB: Uh-huh.

22 MR. SLATER: They sold their API to Teva and they
23 sold it to Torrent. They also manufactured their own
24 finished-dose pills.

25 CHIEF JUDGE BUMB: Right. I got that.

1 MR. SLATER: So we're hearing the Torrent argument,
2 which is the FDA never found our pills to be adulterated. The
3 FDA, once they found ZHP --

4 CHIEF JUDGE BUMB: It doesn't mean that maybe they
5 weren't adulterated. That's all I'm saying.

6 MR. SLATER: Right. And that --

7 CHIEF JUDGE BUMB: So they can argue before the jury
8 all they want, well, the FDA didn't declare it wasn't
9 adulterated. But that argument only goes so far, okay, because
10 you know, maybe the FDA was asleep. Maybe your cGMPs were
11 woefully deficient and they were adulterated. That's what the
12 experts are all going to say.

13 You can make the argument. It gets you halfway.
14 That's it. Maybe not even a quarter of the way. They can make
15 that argument, but it doesn't get them very far.

16 MR. SLATER: And I -- the last thing I just want, so
17 Your Honor knows, the FDA warning letter was directed only to
18 ZHP. And in that warning letter, ZHP was told: Your drugs are
19 adulterated because of your cGMP violations. That covers the
20 entire time the pills were on the market. That's why they put
21 them on an import alert from --

22 CHIEF JUDGE BUMB: No. I think we're all in
23 agreement now.

24 MR. SLATER: Okay.

25 CHIEF JUDGE BUMB: I think there's a dispute about

1 it. I think that the defendants, to the extent that they want
2 to say, well, they weren't adulterated because the FDA said
3 they weren't adulterated until when they did, that argument
4 only gets you so far. Because if I do hear that the jury is
5 somehow being misled to think that the only way a drug can be
6 adulterated is when the FDA says so, that's not correct.
7 That's just not a correct statement of the law, and it's not
8 correct. A drug can be adulterated and the FDA just doesn't,
9 you know, whatever. They weren't doing their job. I don't
10 know.

11 So it's fair game both ways. I just have to be very
12 careful that it's not being misrepresented to the jury.

13 MR. SLATER: And just to be clear, I think Your Honor
14 did rule that the defense cannot say it would be inappropriate
15 to do a retrospective analysis to determine whether the drug
16 was adulterated before the FDA findings.

17 CHIEF JUDGE BUMB: Same reasoning.

18 MR. SLATER: Thank you. Because that was the motion.

19 CHIEF JUDGE BUMB: Same reasoning.

20 MR. SLATER: Thank you.

21 THE COURT: But I don't think that they were going
22 there. But if they were --

23 MR. HARKINS: We --

24 MR. SLATER: I can tell you -- let me just finish,
25 please. I can tell you in the depositions I took of the ZHP

1 witnesses --

2 CHIEF JUDGE BUMB: Yeah.

3 MR. SLATER: -- and their experts, they said it over
4 and over again.

5 CHIEF JUDGE BUMB: And you know what I'm willing to
6 bank on, and then we'll just move on, is I think that there's
7 kind of this disconnect about FDA declaring it versus not
8 declaring it and what really governs for the recalls. I think
9 we kind of squared it. We have to be very precise in our
10 questioning, okay, as to what we're talking about, all right?

11 MR. SLATER: Okay. Yes.

12 MR. HARKINS: Yes.

13 CHIEF JUDGE BUMB: Okay. Second motion.

14 MR. SLATER: The second motion relates to what we
15 believe will become a trial within a trial if allowed.

16 Many of the witnesses have testified and tried to
17 assert that you cannot -- and I'll talk in the context of ZHP,
18 because the defendants -- the testimony may vary somewhat, but
19 I can tell you in the context beginning with ZHP, they
20 repeatedly said how could we have done anything wrong? The FDA
21 didn't know. The FDA didn't say that this was wrong to do.
22 The FDA didn't catch on. Sort of carries on from what Your
23 Honor just said. So we can't have done anything wrong if the
24 FDA didn't even catch on to it.

25 And what they basically want to do is, number one,

1 try to wrap themselves in the FDA as if they didn't have
2 independent obligations to follow all the guidances and all the
3 law that we cite in our brief.

4 CHIEF JUDGE BUMB: That's true. But that all goes to
5 the -- that all goes to the weight of the evidence. I mean, if
6 they want to make that argument, I'm sure you're going to poke
7 holes in it.

8 MR. SLATER: I think so. The second concern is --

9 CHIEF JUDGE BUMB: So I don't know why they would be
10 precluded from making that argument. I just -- I mean, it
11 doesn't get them very far.

12 MR. SLATER: I think the argument --

13 CHIEF JUDGE BUMB: Again, if somehow this jury is
14 being told or misled that the FDA is the be-all and end-all,
15 I'll just have to -- you know, I'll have to, you know, correct
16 the record.

17 But I can't preclude them from saying, well, we
18 relied on the FDA. I mean, I think that's fair game.

19 MR. SLATER: And then I guess that we -- just to
20 square this circle, the other concern we have is that we
21 believe that the defense may want to actually relitigate the
22 FDA findings in the official warning letter that triggered the
23 import alert.

24 CHIEF JUDGE BUMB: A little too late for that.

25 MR. SLATER: We want to make sure they can't do that.

1 CHIEF JUDGE BUMB: Well, how in the world would they
2 do that? Is there any evidence that they tried?

3 MR. SLATER: Well, I think that by disputing whether
4 they violated -- to be fair, the FDA only issued the warning
5 letter to ZHP, so we're talking ZHP right now.

6 CHIEF JUDGE BUMB: Okay.

7 MR. SLATER: The FDA told ZHP: You violated cGMPs in
8 all these different ways in an official warning letter, and
9 your drug was adulterated for that reason, and we're now going
10 to issue an import alert, and this factory that you made this
11 in can't export any more drugs to the U.S.

12 I believe the defense wants to relitigate and say the
13 FDA was wrong, their findings were wrong, and to actually
14 relitigate what the FDA found in the official warning letter
15 leading to an import alert.

16 CHIEF JUDGE BUMB: Okay. And --

17 MR. SLATER: So we don't think that should be
18 permissible. And if Your Honor rules it's not permissible,
19 then --

20 CHIEF JUDGE BUMB: Do you really think that they're
21 going to -- did they dispute the FDA's finding back then? Did
22 they challenge the FDA? Is there evidence in the record that
23 they did not?

24 MR. SLATER: They did not appeal that.

25 CHIEF JUDGE BUMB: Okay. So do you really think

1 they're going to make that argument to the jury?

2 MR. SLATER: I think that's the entire defense,
3 honestly.

4 CHIEF JUDGE BUMB: And then your rebuttal is or your
5 response is, well, a fine time to be attacking the FDA today,
6 five years later.

7 MR. SLATER: I think that is a --

8 CHIEF JUDGE BUMB: I mean, and then you just sort of
9 sit down, don't you, Mr. Slater?

10 MR. SLATER: I would think so. But --

11 CHIEF JUDGE BUMB: So --

12 MR. SLATER: I also don't -- I'm concerned about us
13 spending the time at trial where we have to literally litigate
14 whether the FDA was right or wrong, and it becomes a giant
15 issue that really shouldn't be permitted.

16 CHIEF JUDGE BUMB: But you tell me there was no
17 discovery on it.

18 MR. SLATER: I'm sorry?

19 CHIEF JUDGE BUMB: There's -- there was no -- they
20 didn't appeal the decision.

21 MR. SLATER: Right. They did not appeal to the FDA
22 the findings that --

23 CHIEF JUDGE BUMB: So how -- what evidence would they
24 put in to show me that the FDA was wrong?

25 MR. SLATER: They're going to put their experts on to

1 say our drug wasn't adulterated, we didn't violate cGMPs.
2 That's their defense. We disagree with the FDA. The FDA got
3 it wrong. And then we'd have to literally try what the FDA had
4 available to it, what the FDA saw. And we're going to -- and
5 that is what I think the defense is; that the FDA was wrong in
6 its warning letter.

7 And, in fact, Judge Kugler made a finding, I believe,
8 that if the API was adulterated, the finished-dose pills that
9 contained the adulterated API would be adulterated as well.

10 CHIEF JUDGE BUMB: Right.

11 MR. SLATER: But that's the defense. The defense is:
12 The FDA was wrong. These weren't adulterated pills. We didn't
13 violate cGMPs. And they want to litigate and try that issue
14 and have experts try to poke holes in what the FDA found.

15 CHIEF JUDGE BUMB: Well, they can -- it seems to me
16 it's fair game for them to say that they followed their cGMPs.
17 But to say that the FDA got it wrong when they didn't appeal
18 seems to be a little too late for that.

19 MR. SLATER: And I guess my last question would be,
20 how can they do both? If the FDA -- if they can't challenge
21 the FDA finding, how can they say they didn't violate cGMPs
22 when the FDA said they did?

23 Now, this is ZHP. They didn't make a finding
24 directly against Teva or Torrent, the FDA. There's other -- we
25 believe there's other consequences and repercussions, as I

1 quoted Judge Kugler. But I don't see how the defense can be
2 allowed to relitigate what the FDA did. Otherwise, we're going
3 to try the case on what the FDA did or didn't do.

4 MS. DAVIDSON: Your Honor, if I may.

5 CHIEF JUDGE BUMB: Okay.

6 MS. DAVIDSON: Judge Kugler said something that I
7 think is really important, which was I'm not going to --

8 CHIEF JUDGE BUMB: Can you speak up, please.

9 MS. DAVIDSON: I'm so sorry.

10 Judge Kugler said something I think is very
11 important, which is I'm not going to rehear motions for summary
12 judgment at motions in limine. And, again, I need to point
13 Your Honor again to pages 32 to 34 of the summary judgment
14 ruling which make it very clear --

15 CHIEF JUDGE BUMB: Does anyone have a clean copy of
16 his Opinion?

17 MS. DAVIDSON: You can have my messed-up copy. I
18 don't mind. It's that important that I'm willing to rip it out
19 and give it to you. Can I just read it into the record and
20 then hand it up?

21 CHIEF JUDGE BUMB: Loretta, can you go get me a copy
22 of the Opinion?

23 May I just read it and then I'll hand it back to you?

24 MS. DAVIDSON: Sure, Your Honor. May I approach?

25 CHIEF JUDGE BUMB: Yes.

1 MS. DAVIDSON: Pages 32.

2 CHIEF JUDGE BUMB: Pages 32 to 34?

3 MS. DAVIDSON: Uh-huh.

4 (Court reading.)

5 CHIEF JUDGE BUMB: Okay. So what is the point that
6 you want to make?

7 MS. DAVIDSON: So, Your Honor, I think this goes to
8 the next couple of motions in limine, which is we do have a
9 right to put on a defense. And we are allowed in our defense
10 to explain what the FDA did, when it did it, what the FDA said,
11 when it said it.

12 And all of these motions are seeking to preclude us
13 from introducing relevant evidence.

14 CHIEF JUDGE BUMB: You're permitted to put on what
15 the FDA did, what the FDA said, when the FDA declared that it
16 was adulterated.

17 You're also permitted to put on evidence as to
18 whether or not you complied with GMPs. They're entitled to put
19 in evidence that you didn't comply and as a result the drugs
20 were adulterated. I don't know what the quarrel is all about.

21 MS. DAVIDSON: I -- we agree with everything you just
22 said. Again, these are not our motions to exclude. We're just
23 trying to preserve our ability to introduce relevant evidence
24 from the FDA and make sure that the FDA's story is complete.

25 CHIEF JUDGE BUMB: What did I say that was just

1 wrong, Mr. Slater?

2 MR. SLATER: Absolutely nothing. I'm not taking --
3 I'm not quarreling. I understand your ruling, Your Honor.

4 I think that, as may happen from time to time, we've
5 sort of gone beyond the motion into another obviously important
6 issue that was further in the brief. I just wanted to bring
7 back just to this one motion that --

8 CHIEF JUDGE BUMB: What is the motion?

9 MR. SLATER: We want to preclude the defense from
10 arguing that the contamination was the FDA's fault or was
11 unavoidable because the FDA did not prevent it or realize that
12 this could happen.

13 Essentially, a lot of witnesses -- this is not coming
14 from thin air. It's coming from the testimony we've gotten
15 where witnesses continually said --

16 CHIEF JUDGE BUMB: That the FDA should have caught
17 this earlier?

18 MR. SLATER: Yeah. That the FDA didn't catch it.
19 They should have done it. They should have found out, and they
20 don't -- they didn't --

21 CHIEF JUDGE BUMB: Is anyone over on this side of the
22 aisle going to make that argument? Because I would be very
23 shocked that you're going to make that argument to the jury.
24 Are you going to make that argument to the jury, that the FDA
25 should have caught this earlier?

1 MS. ROSE: Your Honor, no, not in the way Mr. Slater
2 is portraying it.

3 There is an element of this where the FDA did review
4 the drug master file that explained detail by detail how the
5 valsartan API was made, what chemicals were used, all of those
6 things.

7 CHIEF JUDGE BUMB: Okay.

8 MS. ROSE: And there's evidence that the FDA looked
9 at it, very experienced FDA chemists, and said, okay, this is
10 approved, we don't see that this is going to cause NDMA. They
11 didn't raise an issue.

12 Now, one of plaintiffs' arguments is any reasonable
13 chemist should have looked at this formula and said this is
14 going to create NDMA or NDEA. But you had very experienced FDA
15 chemists look at it and not raise an issue. So we think that's
16 relevant. We're not going to blame the FDA.

17 CHIEF JUDGE BUMB: That -- okay.

18 MS. ROSE: But it just goes to the point of what was
19 knowable and in the scientific knowledge at the time.

20 CHIEF JUDGE BUMB: Okay. They're not going to blame
21 the FDA.

22 MR. SLATER: Well, so this is -- well, what they're
23 saying, not only do they want to -- I think we'll see how it
24 plays out, but what they're talking about there is saying you
25 can't find us responsible because the FDA didn't catch it, so

1 how can you expect us to catch it if the FDA didn't?

2 CHIEF JUDGE BUMB: They're not making that argument.
3 They're not making that argument. They're saying that a
4 chemist --

5 MR. SLATER: I think that's what she just said.

6 CHIEF JUDGE BUMB: Well, no. An FDA chemist looked
7 at it, an FDA chemist looked at it and made the following
8 finding.

9 Your testimony or your evidence will be a chemist
10 would look at this and make a different finding. And so that
11 argument, again, it only goes so far. I don't know what the
12 chemist looked at. What if he looked at a, you know, cartoon?
13 I don't know.

14 MR. SLATER: Well, the other thing is we actually --
15 we know what their general policies are, perhaps. But there's
16 actually no evidence that any particular chemist looked at any
17 specific thing at any particular time.

18 CHIEF JUDGE BUMB: Okay.

19 MR. SLATER: So I don't know how they can make that
20 argument.

21 CHIEF JUDGE BUMB: That's not -- that's not what was
22 just represented to me.

23 MR. SLATER: And who's that chemist? And do we get
24 to cross-examine that chemist? I mean, we don't have any
25 identification of that specific chemist.

1 CHIEF JUDGE BUMB: Who are you talking about?

2 MR. SLATER: Yeah. Who's the chemist?

3 MS. DAVIDSON: Adam, you have the right to
4 cross-examine our witnesses. We're just asking for our
5 witnesses to be allowed to provide relevant testimony.

6 CHIEF JUDGE BUMB: Who is the chemist that will say
7 I've looked at this and there's no impurities, it's not
8 adulterated or whatever? Who is it?

9 MS. ROSE: So we, defendants are not privy to who
10 exactly at the FDA reviewed the DMF submission. It's just not
11 information we have.

12 THE COURT: No. What you just said to me earlier.
13 Who is that witness going to be?

14 MS. ROSE: I'm sorry. Oh, who is our witness who's
15 going to explain that the FDA reviewed the drug master file?

16 CHIEF JUDGE BUMB: Yeah.

17 MS. ROSE: That -- I think several witnesses could
18 testify, but Dr. Ali Afnan who we talked about earlier explains
19 it in depth in his report. That that is the process by which a
20 drug, an Abbreviated New Drug Application, so that would be the
21 valsartan drug, in order for that to be approved, which it was
22 in 2015, they have to look at the drug master file for the API,
23 which the FDA did. And the FDA said there was not a problem
24 with the API.

25 So --

1 CHIEF JUDGE BUMB: Yeah. That's kind of an apples
2 and oranges kind of a thing going on again.

3 MR. SLATER: Yeah. I mean, counsel just said they
4 don't know who reviewed the DMF at the FDA.

5 CHIEF JUDGE BUMB: Yeah.

6 MR. SLATER: So it is --

7 CHIEF JUDGE BUMB: So I think this comes under
8 needless anxiety. We'll move on.

9 MR. SLATER: I'm sorry, what was that?

10 CHIEF JUDGE BUMB: This comes under the category of
11 needless anxiety on your part. We'll move on.

12 MR. SLATER: Okay. Thank you, Your Honor.

13 CHIEF JUDGE BUMB: I don't think that testimony is
14 coming in.

15 MS. LOCKARD: Just -- can I make sure I understand
16 this ruling?

17 I believe we are on Plaintiffs' Motion No. 2 of 2648.
18 And one of the things that Teva wants to be able to say,
19 putting ZHP aside, you've heard about how the FDA reviewed
20 their DMF and so forth, when Teva learned that there was a
21 process change with the API and ZHP, Teva submitted the process
22 change information to FDA. So everything we knew from ZHP,
23 Teva relayed to the FDA. FDA looked at it and approved it. We
24 just want to be able to say that; that that in fact occurred,
25 which it did.

1 So as Your Honor said, what the FDA did and when they
2 did it and what they said and when they said it is in, just
3 want to make sure that's clear.

4 Plaintiffs can then cross-examine our witnesses and
5 our experts and our company witnesses to say, well, yeah, but
6 you know, the FDA didn't have all the information or, you know,
7 whatever they're going to say to that.

8 But I just want to make sure we're able to get out in
9 front of the jury and present the facts as they are, which is
10 that we've presented a process change to the FDA, they reviewed
11 it. So --

12 CHIEF JUDGE BUMB: Yeah. I don't -- do you see any
13 problem with that, Mr. Slater, what they're arguing? I mean,
14 to me it's sort of like, you know, they proceed at their own
15 peril.

16 MR. SLATER: Yeah. I think Mr. Stanoch is going to
17 say that they actually didn't submit the full process change.
18 I thought they actually --

19 MS. LOCKARD: And that's subject to
20 cross-examination.

21 MR. SLATER: They didn't have it.

22 CHIEF JUDGE BUMB: So here's the deal: The
23 defendants are permitted to -- I mean, they're facts. What the
24 FDA did, what the FDA didn't do, they're permitted to say all
25 of that. They're permitted to say, you know, this is what

1 happened. Chemist walks in or they'll -- I don't know that
2 there's now a chemist from the FDA. But that doesn't mean that
3 the FDA was looking under the hood. That doesn't mean that
4 they were following their GMPs correctly and they should have
5 been.

6 So that argument about what the FDA did and didn't
7 do, it really only gets them so far.

8 MR. SLATER: I agree. But it's going to subsume a
9 tremendous amount of time.

10 CHIEF JUDGE BUMB: Why?

11 MR. SLATER: Because --

12 CHIEF JUDGE BUMB: This is what they did and we moved
13 on. Isn't the jury going to say, "yeah"?

14 It's kind of like -- it's kind of like, you know, the
15 IRS comes to look at your tax records, your records, and you
16 only show them a little bit. Oh, fine. No problem. And then,
17 you know, you start digging deeper and it's like, oh, you got a
18 problem.

19 You think you're going to rely on, well, they came
20 and audited me and that was fine, when you hid half the
21 documents from them? I mean, that's kind of what we're talking
22 about here.

23 MR. SLATER: But that's not what they're saying.

24 CHIEF JUDGE BUMB: Yes, it is.

25 MR. SLATER: They're not going to tell that --

1 they're going to tell the jury the FDA had everything and they
2 didn't pick up on this. But I don't think Teva even submitted
3 the process change with all the details because I don't think
4 Teva had it. So I don't know how they could have done that
5 with what counsel just said.

6 CHIEF JUDGE BUMB: Well, it's a little too late in
7 the game. I mean, either the FDA had it all or they didn't
8 have it all.

9 MR. SLATER: Correct.

10 CHIEF JUDGE BUMB: Right. So --

11 MR. SLATER: I -- I guess, Your Honor, we'll see how
12 it plays out. But I think what we're setting up here is a big
13 battle at trial about what the FDA had, didn't have, what the
14 FDA does, how they do things. I mean, I think you ruled on the
15 motion already, I think. Now we're kind of going into the
16 aftermath of it, but that's what we want to avoid, is this
17 trial shouldn't be a trial about the FDA. It should be a trial
18 about whether these defendants met their regulatory obligations
19 and whether they breached the law.

20 CHIEF JUDGE BUMB: That's the focus. That's right.

21 MR. SLATER: But they want to say, well, don't look
22 at what we did or didn't do. Look at the fact that the FDA
23 didn't catch it either, and that's how they want to defend the
24 case. Like, don't look at us, look over there, because if the
25 FDA didn't catch it, how can you blame us?

1 CHIEF JUDGE BUMB: You really think they're going to
2 make that argument to the jury?

3 MR. SLATER: That's the defense to the case. I
4 took -- I can't count how many depositions I took. That's what
5 we got over and over from witnesses, yes.

6 CHIEF JUDGE BUMB: Okay.

7 MS. LOCKARD: On behalf of Teva, Mr. Slater did not
8 take any of Teva's witnesses. So what I would like to say is
9 that that's -- Your Honor's instinct is correct. That's not
10 going to be our defense.

11 What we are intending to do, and I think what we're
12 entitled to do, is to present this situation in the context in
13 which it unfolded according to the facts. There are FDA rules
14 and regulations. They say we violated them. We will say we
15 complied. FDA issued the recall. That is the whole umbrella
16 in which this case came to be. So we cannot divorce this case
17 from what is going on with the FDA. We don't intend to blame
18 FDA. You know, we will have to answer to plaintiffs and their
19 cross-examination for any misgivings or failures. But I think
20 we are enabled to say these are the rules, we either followed
21 them or we didn't, and this is what FDA said about it.

22 CHIEF JUDGE BUMB: And so I'll just end it by saying
23 that I guess to the extent that the plaintiff is seeking that
24 the defendants not be permitted to blame it on the FDA, the
25 defendants will proceed at their own peril.

1 MS. DAVIDSON: Thank you, Your Honor.

2 CHIEF JUDGE BUMB: Okay. What's the next motion?

3 I need to move this along. "Cannot blame third
4 parties, including prescribing physicians, the FDA, or others,
5 for the damages at issue." That's true. Can't.

6 You can talk about the facts, but, you know, I don't
7 know how -- I don't know how you can -- how in the world can
8 you blame physicians?

9 MS. BRANCATO: No, Your Honor. You're absolutely
10 correct. And it wasn't our plan to do so.

11 THE COURT: Yeah.

12 MS. BRANCATO: We just want to talk about the facts
13 and the facts that doctors prescribe these medications. After
14 the recall, they would have had to prescribe something else, et
15 cetera, that's it.

16 CHIEF JUDGE BUMB: Yeah. I -- okay. Right. Okay.

17 Four, "Defendants cannot assert that the FDA's
18 statement advising patients not to discontinue their use of the
19 VCDs until they could obtain a prescription for a replacement
20 medication or treatment meant that the FDA did not believe that
21 there was an unacceptable health risk due to the contamination
22 of VCDs."

23 Yeah, that they can't do. That's just not -- that's
24 a distortion of the record.

25 MS. DAVIDSON: Your Honor, if I may, one of the

1 problems is that these titles don't match what the substance of
2 these motions in limine say.

3 CHIEF JUDGE BUMB: Yeah.

4 MS. DAVIDSON: So the motion in limine essentially
5 seeks to actually exclude these FDA statements. And that's the
6 problem, right? Plaintiffs are seeking to exclude any FDA
7 statements except the warning letter, to prevent -- to present
8 the jury with a very one-sided picture.

9 We're saying that all statements by the FDA come in.
10 We're not planning to blame. Like, all these pejorative terms
11 in the titles don't reflect our defense. But the actual
12 substantive evidence, we want to make sure that it's understood
13 that that is admissible.

14 CHIEF JUDGE BUMB: What do you want to do on four?

15 MS. LOCKARD: May I be heard, Your Honor? This is
16 very, very simple. The FDA --

17 CHIEF JUDGE BUMB: It's not your motion, though.

18 What do you want by this motion?

19 MR. SLATER: Simply what I think Your Honor
20 understood, which is the FDA, when this came out, they said:
21 Don't stop taking your pills until you go to your doctor and
22 they put you on something else so you don't die of a stroke or
23 a heart attack.

24 CHIEF JUDGE BUMB: Okay. That does not equate to the
25 fact that we don't -- that we "oops" on the recall. They can't

1 say that, okay. Granted.

2 MS. LOCKARD: Right. No one is going to say that it
3 doesn't mean there was an issue with these drugs.

4 CHIEF JUDGE BUMB: Yes.

5 MS. LOCKARD: The issue in the case is the worth of
6 the drugs and the worthlessness of the drugs.

7 CHIEF JUDGE BUMB: I know.

8 MS. LOCKARD: And the efficacy and the safety of the
9 drugs. And worth is inherently tied to whether or not there
10 was any benefit to continue taking these drugs --

11 CHIEF JUDGE BUMB: Right.

12 MS. LOCKARD: -- even for a short period of time.

13 CHIEF JUDGE BUMB: Right.

14 MS. LOCKARD: The FDA told people to continue taking
15 these drugs around the country. They told physicians to
16 keep --

17 CHIEF JUDGE BUMB: For a short time because there
18 wasn't anything available.

19 MS. LOCKARD: Right.

20 CHIEF JUDGE BUMB: You can make that argument.

21 MS. LOCKARD: Okay. And Summa and Emblem, the
22 plaintiffs, the TPPs in this case, likewise told their
23 affiliates and their insureds.

24 CHIEF JUDGE BUMB: Right. You had to pick your
25 poison. Die of a heart attack or die of cancer. Okay.

1 Next motion.

2 MS. LOCKARD: So we can produce and introduce that
3 statement by the FDA, then?

4 CHIEF JUDGE BUMB: Yeah. It's in the record.

5 MS. LOCKARD: Okay.

6 CHIEF JUDGE BUMB: But what you can't say is: And by
7 definition, therefore, the FDA believed it wasn't adulterated.

8 MS. LOCKARD: Okay.

9 CHIEF JUDGE BUMB: And that there was no unacceptable
10 health risk. You can't do that. That's not what the FDA said.
11 What the FDA said, you got to pick your -- you got to pick the
12 worst of two evils. I'm paraphrasing here.

13 MS. LOCKARD: I just want to be clear that that
14 motion was denied for the record.

15 MR. SLATER: What?

16 CHIEF JUDGE BUMB: No. Actually, it was granted.

17 MS. LOCKARD: But you said we could introduce that
18 statement to show what FDA said.

19 CHIEF JUDGE BUMB: Yes.

20 MS. LOCKARD: Their motion is to exclude that
21 statement.

22 CHIEF JUDGE BUMB: No. The motion is -- let's
23 just -- let's not pay attention to these labels.

24 MR. SLATER: It was not to exclude the statement.

25 CHIEF JUDGE BUMB: You just don't want them arguing

1 to the jury that that statement meant that the FDA thought that
2 there was no health risk associated with the drug.

3 MR. SLATER: Yes.

4 CHIEF JUDGE BUMB: Okay.

5 MS. LOCKARD: Okay.

6 MS. DAVIDSON: Your Honor, in fairness, this motion
7 in limine says because the FDA's short-term advice on patients'
8 transition to safe treatments has absolutely no probative value
9 and would only be used to confuse and mislead the jury, it
10 should be excluded. That's, I think, why Victoria is
11 concerned. The motion itself says that the entire statement
12 should be excluded.

13 CHIEF JUDGE BUMB: Can we have an agreement?

14 MR. SLATER: Your Honor, I just agreed. I thought
15 that we --

16 CHIEF JUDGE BUMB: Can we just have this agreement?

17 Because you folks tend to write briefs that kind of
18 snap at each other, unnecessarily so, I might say, I think I
19 said that earlier. I think it's going to be far more
20 productive if, Mr. Slater, you stand up and you tell me what
21 relief you're seeking for and then you all respond. I don't
22 find it productive to go back and argue about what's in the
23 papers, because we're going to have nicely written papers from
24 now on.

25 Okay. Your next motion.

1 MR. SLATER: The next motion is brought under
2 Rule 403.

3 CHIEF JUDGE BUMB: Okay.

4 MR. SLATER: There are two statements that were
5 issued informationally by the FDA at different points in time
6 after this had all been announced, giving background
7 information, explaining what was going on, explaining what the
8 FDA was doing.

9 There are things, and they're informational, they're
10 not official warning letters or anything. They're
11 informational statements.

12 CHIEF JUDGE BUMB: Okay.

13 MR. SLATER: And there's something for everybody in
14 them. In some of them, in some of the statements, and I
15 pointed out that Dr. Afnan attempted to -- he attempted to rely
16 in part, but the opinion was precluded, but I think it's
17 illustrative that the FDA said in January 2019, this
18 informational press release, that the FDA's investigation into
19 ZHP's process identified that a change made to the
20 manufacturing process likely led to this impurity and that the
21 impurity went undetected by global regulators, including the
22 FDA, for a period of time.

23 CHIEF JUDGE BUMB: What's the relief you're seeking?

24 MR. SLATER: I'm sorry?

25 CHIEF JUDGE BUMB: What's the relief you're seeking?

1 MR. SLATER: I'm seeking to keep these statements out
2 because they're going to be argued by the defense, well, the
3 FDA said nobody could have known; and then we're going to point
4 to the parts of the statements where they actually specifically
5 quoted that they issued a warning letter to ZHP and found
6 problems. And it's going to end up becoming a 403 issue.

7 CHIEF JUDGE BUMB: They come into -- they're
8 permissible to come into evidence. If I have to give a
9 limiting instruction as to what the jury can consider them for,
10 I will. I think that what the parties are trying to do is
11 they're trying to put way too much emphasis on the FDA and the
12 FDA's import.

13 There is a difference in my mind whether or not the
14 FDA declared them adulterated. Whether or not the FDA found
15 them adulterated does not mean in fact that they were not
16 adulterated earlier on.

17 And any statements to the contrary, you know, could
18 be misleading to the jury. And so if I find that all the jury
19 is hearing is, well, the FDA this and the FDA that, I'll have
20 to just give limiting instructions; that just because the FDA
21 said it was so or wasn't so, doesn't mean it wasn't so.

22 I mean, that's just how it is going to have to go,
23 okay? So I guess reserved in part.

24 Okay. Next motion.

25 MR. SLATER: The next motion is to preclude the

1 defendants from arguing that the industry -- that as a matter
2 of industry standards, there was no obligation or no
3 possibility of them being able to know that this was going to
4 happen, guard against the potential contamination, et cetera.
5 And that's come from experts and witnesses that have testified.

6 We quoted here in our brief that the FDA explicitly
7 rejected that argument in the warning letter to ZHP and said --
8 it's on page 9 of our brief at the bottom -- "We remind you
9 that common industry practice may not always be consistent with
10 cGMP requirements and you are responsible for the quality of
11 drugs you produce."

12 So ultimately, what I'm asking is to preclude the
13 defense from saying, well, this was an industry issue and
14 nobody knew as opposed to defending their own conduct based on
15 what they did or didn't do based on the regulations.

16 CHIEF JUDGE BUMB: If they make that argument, I'll
17 give a limiting instruction.

18 MR. SLATER: Okay. And I think -- actually, I don't
19 have to say anything else on that.

20 CHIEF JUDGE BUMB: Okay. Next motion.

21 MS. ROSE: Sorry, Your Honor. I just wanted to be
22 clear on what the ruling was.

23 CHIEF JUDGE BUMB: The ruling is, is that if you
24 misrepresent the state of the law, I'll give a limiting
25 instruction.

1 So if you get up and say that industry practice is
2 what governs, and it's really not, it's cGMP requirements, you
3 can get up and talk about industry practice, but if you're
4 hanging your hat on that, you're doing it at your own peril.

5 MS. ROSE: Understood, Your Honor.

6 CHIEF JUDGE BUMB: Okay. Next motion.

7 MR. SLATER: Thank you.

8 The next motion is to preclude hearsay testimony of
9 Jucai Ge, a corporate representative of ZHP, from testifying
10 that she had an ex parte conversation -- "ex parte" is probably
11 not the right word. She had a conversation with Jinsheng Lin
12 who wrote the July 27, 2017 email. And in that conversation he
13 said, well, I didn't really mean what it says. I'm
14 paraphrasing obviously. We laid out the language and gave you
15 the exact testimony that it was, I thought, a good
16 illustration. That's obviously hearsay. She's a corporate
17 rep. She can't --

18 CHIEF JUDGE BUMB: Granted. Next motion.

19 MR. SLATER: Thank you.

20 MS. ROSE: Your Honor, may I be heard?

21 CHIEF JUDGE BUMB: Yeah.

22 MS. ROSE: Thank you.

23 This motion is actually moot based on Your Honor's
24 rulings earlier today.

25 CHIEF JUDGE BUMB: Yeah.

1 MS. ROSE: When you were talking about bringing
2 witnesses live. Jinsheng Lin is one of the witnesses that ZHP
3 is going to be bringing live.

4 CHIEF JUDGE BUMB: Right. But he --

5 MS. ROSE: And also so is Jucai Ge. She will not be
6 testifying -- providing hearsay testimony about his statements.

7 CHIEF JUDGE BUMB: Dr. Lin?

8 MS. ROSE: Because Dr. Lin will be here to testify.
9 He'll talk about his own statement.

10 CHIEF JUDGE BUMB: No. But the motion is to prevent
11 her from testifying about what Dr. Lin told her. That's
12 hearsay.

13 MS. ROSE: Sure. It's my understanding the motion
14 was based on the admission of Jucai Ge's deposition testimony,
15 where she was asked about Mr. Lin's -- things that she had
16 discussed with Mr. Lin. But you ruled earlier that her
17 deposition testimony was no -- at this point she will be
18 testifying live. So we're dealing with her live testimony now.

19 CHIEF JUDGE BUMB: Right. But if you were to ask her
20 on direct examination, what did Dr. Lin tell you --

21 MS. ROSE: Oh, okay. Understood.

22 CHIEF JUDGE BUMB: If it's being offered for the
23 truth of the matter, that's rank hearsay.

24 MS. ROSE: Got it. Yeah. We understood it as moot
25 because she'll be testifying live and so will Dr. Lin.

1 CHIEF JUDGE BUMB: Well, I'm just foreseeing that you
2 may want to ask the same question live, so...

3 MS. ROSE: Understood. Thank you.

4 CHIEF JUDGE BUMB: Okay. Next motion.

5 MR. SLATER: The next motion is to preclude the
6 defendants -- and this is a motion we were surprised we had to
7 file. Obviously there was a lot of meeting and conferring and
8 discussions between the parties -- that the defendants should
9 not be able to say to the jury that the substances at issue,
10 NDMA and NDEA, are not and were not always known to be
11 genotoxic, probable human carcinogens. That was in the
12 scientific literature long before any of this happened. It's
13 in the regulatory guidances that govern their conduct. So we
14 don't believe they should be allowed to come in and dispute
15 what is an immutable fact and would be highly misleading to the
16 jury.

17 CHIEF JUDGE BUMB: Okay.

18 MR. HARKINS: Your Honor, the defendants do not
19 dispute that the IARC classification and other scientific
20 material states that these substances in the abstract are
21 genotoxic and classify them as a probable human carcinogen.
22 All we are seeking to ensure is that we are allowed to present
23 evidence that the levels present in the pills, the levels that
24 are actually at issue in the medication, is not known to be
25 carcinogenic to humans.

1 Similar evidence about the existing limits in place
2 by the FDA which do allow the presence of these exact compounds
3 to be present in medication. Things like that, we do think we
4 still need to be able without creating a whole side trial on
5 the specific general causation issue, we do think we need to be
6 able to respond to the classifications, which we do not
7 dispute, and put in context what those substances mean at the
8 levels that are present in the pills.

9 CHIEF JUDGE BUMB: Okay.

10 MR. SLATER: So the motion that we're talking about,
11 number 8 --

12 CHIEF JUDGE BUMB: Is granted. They're not going to
13 dispute that it's a carcinogen, a known carcinogen. They just
14 want to talk about dosage, which we'll get to.

15 MR. SLATER: Which is motion 9.

16 CHIEF JUDGE BUMB: Okay.

17 MR. SLATER: So motion 9 is that general causation is
18 not an element, should not be referenced. And dosage is
19 specifically a general causation issue.

20 Basically what the defense wants to say is there
21 wasn't enough in these pills to give somebody cancer, and
22 that's not the issue in this trial. In a personal injury case,
23 they can make those arguments. But in this case it was a
24 regulatory determination based on -- and I'm quoting ZHP -- "an
25 unacceptable carcinogenic risk." That's why the pills were

1 pulled off the market because of the risk level. We don't have
2 to prove anybody got cancer. We don't have to prove the dose
3 was enough to give cancer to anybody. We have to be able to
4 prove, as occurred, that because of the levels of
5 contamination, because these were contaminated, the pills had
6 to be pulled off the market and could not be sold. So dose is
7 a general causation concept. So dose should not come in.
8 Otherwise, we're going to, again, have a side trial about,
9 well, was there enough? Was there not enough? What cancer
10 could be caused? How many times would you have to take the
11 pills? None of that matters for this trial.

12 CHIEF JUDGE BUMB: Can I ask who would like to answer
13 this question: Is it really the defendants' intent to argue to
14 this jury or to say to this jury, yeah, there was carcinogen in
15 the pill but not enough to kill you?

16 MS. LOCKARD: I don't think anyone will come into
17 court and argue that.

18 CHIEF JUDGE BUMB: Where do you want to go with this?

19 MS. LOCKARD: I think the issue in this case is it's
20 an issue of the worth of the medication and the worthlessness
21 that they allege.

22 CHIEF JUDGE BUMB: Do you -- so -- no. I understand
23 what the argument is.

24 So --

25 MS. LOCKARD: Well, it's axiomatic that the worth of

1 a medication derives from its safety and its efficacy. They
2 are cutting us off from any ability to talk about the safety of
3 the drug.

4 CHIEF JUDGE BUMB: That's what I'm asking you. Are
5 you really going to say to the jury it's just not enough to
6 kill you?

7 MR. OSTFELD: Yes.

8 MS. LOCKARD: We have -- yes. We have a Lewis
9 Chodosh, who is an MIT, Harvard, Yale cancer biologist who
10 testified to that based on the scientific literature in his
11 deposition. And I don't think this is going to take two weeks
12 to bring this to the Court's attention.

13 But for us to be able to be, you know, muzzled on
14 this when plaintiffs are going to come in and the first words
15 out of their mouth in their opening is: Carcinogen, cancer
16 causing. And they're going to put up all of these cancer
17 language, and we're not going to be able to say, yes, it's
18 true, NDMA has been recognized as a carcinogen, but let's tell
19 the full story. Look at the amounts, the dosage. The
20 literature doesn't support that that dose level will cause
21 cancer. And we don't -- we don't have to prove that anybody
22 caused the cancer.

23 CHIEF JUDGE BUMB: But aren't you ignoring the fact
24 that you couldn't sell it anyway? Isn't that really what the
25 case is about? You could not sell it because of the recall,

1 right?

2 MS. LOCKARD: Well, and that's certainly an argument
3 that they can make. But just because we couldn't sell it, as
4 our damages experts have said, it doesn't mean it's completely
5 worthless. It still provided a benefit to the individuals who
6 got it. So --

7 CHIEF JUDGE BUMB: For that -- for that limited
8 period of time?

9 MS. LOCKARD: For that period of time.

10 So, sure, their argument, their argument, and they
11 will make it very well, and persuasively I'm sure, to the best
12 of their ability, that because it was recalled and it was
13 adulterated, therefore, it is of zero value.

14 Our position is different. Our position is that you
15 can't just make that determination based on those only two
16 factors. The other factors are the safety and efficacy of the
17 drug, and we should be able to make that argument to the jury.
18 We're not going to ask them if anybody's cancer was caused by
19 it. It won't be on the jury form, but it is --

20 CHIEF JUDGE BUMB: No. But can you answer this
21 question: How does it have any value when it's been recalled
22 and you can't sell it? Can you answer that question?

23 MR. OSTFELD: Your Honor, this actually rolls into a
24 different motion in limine. There's a separate motion in
25 limine on worthlessness. It's Motion No. 22.

1 CHIEF JUDGE BUMB: Your motion or theirs?

2 MR. OSTFELD: It's plaintiffs' motion.

3 Oh. It's Motion No. 17, that defendants cannot
4 assert that the contaminated valsartan-containing drugs had
5 value on their -- had value based on their efficacy.

6 And if Your Honor likes, I'd be happy to address that
7 now because I think the argument on this motion is sort of
8 rolling into the argument on value and efficacy.

9 CHIEF JUDGE BUMB: Yeah.

10 MR. OSTFELD: But the question --

11 CHIEF JUDGE BUMB: I'm just -- I'm just -- I want to
12 make sure that I understand the argument that's going to be
13 presented to the jury.

14 MR. OSTFELD: Yes, Your Honor. Well, I think Judge
15 Kugler identified this as one of the core issues that's going
16 to have to go to the jury: The question of value and the
17 question of worthlessness. Because remember, we're not just
18 talking about the value of the product that was pulled from the
19 shelves. We're talking about the value of the valsartan that
20 was taken by patients for years prior to the recall.

21 What plaintiffs' expert, Dr. Rena Conti, has said is
22 all of that valsartan going back in time was worthless because
23 now it is not legal to sell. Essentially, the proposition that
24 Your Honor just asked, how can it have value if it was
25 recalled?

1 What our economist --

2 CHIEF JUDGE BUMB: You're talking about the
3 pre-recall, okay. I got it.

4 MR. OSTFELD: Yes, Your Honor.

5 Our economist, Dr. Lauren Stiroh, says that's not how
6 you value a drug. Patients took this drug for years. They had
7 effective hypertension treatment. Effective hypertension
8 treatment has value. Therefore --

9 CHIEF JUDGE BUMB: It's a jury question. Jury
10 question.

11 MR. OSTFELD: Yes. That's all.

12 CHIEF JUDGE BUMB: Jury question.

13 MR. SLATER: On the efficacy issue?

14 CHIEF JUDGE BUMB: It's a jury question whether or
15 not the drug had value pre-recall.

16 MR. SLATER: No; yeah. We understand that.

17 CHIEF JUDGE BUMB: Yeah.

18 MR. SLATER: As far as this issue about dose and
19 general causation evidence coming in, that should not be -- I
20 assume that's not coming in, though, as part of their argument?

21 CHIEF JUDGE BUMB: I was addressing the motion.

22 MR. SLATER: Right, on 17.

23 CHIEF JUDGE BUMB: And now what's the motion on 9?

24 MR. SLATER: Nine was to preclude any -- to preclude
25 the concept of general causation from the trial. And we gave

1 the example of dose, which is really where you see that the
2 issue is joined, and the defense wanted to argue, well, it
3 wasn't contaminated that much so it had value because it wasn't
4 contaminated enough to give you cancer. That's what they want
5 to argue.

6 CHIEF JUDGE BUMB: Well, doesn't that just sort of
7 roll into the motion we were just resolving on -- deciding?

8 MR. SLATER: It's --

9 CHIEF JUDGE BUMB: I mean, they seem very similar to
10 me. I think we're getting a little too -- aren't they sort of
11 one and the same?

12 MR. SLATER: No. I think they're very different.

13 CHIEF JUDGE BUMB: Well, they're permitted to say
14 that it had some value, it hadn't been recalled yet, they were
15 permitted to sell it, and it had efficacy because it was
16 working, but nobody knew it had a carcinogen in it. And why
17 can't they then say: "And there was very little in it"?

18 MR. SLATER: Well, once they say "there was very
19 little in it," we're trying general causation. Because I'll
20 tell you for example. And this is, for background, this is on
21 page 2 of our brief. It's from a different motion, but it's
22 directly applicable here.

23 This was always, always inappropriate. You could
24 never have NDMA or NDEA in the pills. In fact, the FDA
25 *Guidance for Industry: Genotoxic and Carcinogenic Impurities*

1 in Drug Substances and Products from 2008 said, "There are some
2 compounds containing certain structural groups, aflatoxin-like,
3 N-nitroso," which is the nitrosamines, including NDMA and NDEA,
4 "and azoxy-containing -- and azoxy-structures that have
5 extremely high carcinogenic potency and are excluded from the
6 threshold approach." meaning you don't look at how much is
7 there. You have to do -- there's a simple threshold. You have
8 to actually analyze it.

9 And then the guidance also says: "Every feasible
10 technical effort should be made to prevent the formation of
11 genotoxic or carcinogenic compounds during drug substance
12 synthesis or drug product manufacturing."

13 CHIEF JUDGE BUMB: Yeah.

14 MR. SLATER: So I'm stopping there to say this was
15 always precluded. This wasn't something where after the fact
16 the FDA woke up and said, oh, that's bad stuff. It was always
17 precluded to happen. There was zero allowed in the pills.

18 CHIEF JUDGE BUMB: And you'll make that. And you can
19 introduce that evidence. That's fair. That's fair.

20 MR. SLATER: Now, the flip side -- now getting to the
21 general causation.

22 CHIEF JUDGE BUMB: Yeah.

23 MR. SLATER: If the defense were allowed to say,
24 well, you know what, it was such a little bit that it probably
25 wouldn't cause anyone cancer or wouldn't cause anyone cancer so

1 that doesn't impact the value, then we're going to come back
2 with, for example, as we stated on page 19 of our brief, the
3 Gomm study, which was a retro -- an RCT that was conducted on
4 people who took these valsartan pills, and they found a
5 statistically significant increased risk of liver cancer for
6 people who actually took these pills. And then they're going
7 to say, well, there's this other study and this other study.

8 Dose is general causation, which is the slope to the
9 mini trial on general causation, which is not an element of any
10 of our claims.

11 CHIEF JUDGE BUMB: How do you get into the -- why is
12 the dosing -- why is the dose relevant other than causation?

13 MS. LOCKARD: It is relevant to causation, but
14 causation is relevant to the worthlessness in this case. And
15 we are -- Mr. Slater, respectfully, is talking about propriety
16 of whether this should have been in the drug. That's not what
17 this motion is about. It's about allowing us simply to explain
18 based on the dose level and the scientific literature that
19 exists, Pottegard, Mansouri, we'll talk about, we're prepared
20 to talk about those today, and our cancer biologist to say,
21 look, okay, NDMA, plaintiffs are going to say it's a scary
22 carcinogenic. We should be able to bring in our expert to say,
23 look, but you have to, like in any case, it's the dose that
24 matters. You have to look at the dose to see is it really that
25 dangerous.

1 And the reason that's relevant is because we're
2 talking about whether the product had any value or worth
3 pre-recall. In order to look at that, you have to look at the
4 safety and the efficacy. How can you look at the safety if you
5 don't look at this very issue?

6 And it is a common issue. It has been since the
7 inception of this case. The JPML said whether the medication
8 presented a risk of cancer is a common question of fact, in all
9 cases. They would not have transferred these TPP cases into
10 this MDL if not. Judge Kugler, likewise, and we cited him in
11 our brief multiple times, but also said in 2022, when he set
12 this TPP trial, he said: The first and most important question
13 here, which is general causation. So we'll pick a case,
14 probably a TPP case because damages are relatively easy to
15 calculate, and just to get a jury to say yes or no on the
16 question of general causation and get that done. That was what
17 was said when we first heard about a TPP trial.

18 Even farther back, in 2019, Judge Kugler said:
19 Causation carries over. If the contamination is not dangerous,
20 then maybe they don't have such a great argument that they
21 should get their money back. And that's all we're saying.
22 This is something that could be presented in a very streamlined
23 way with a limited number of witnesses. There are not gobs and
24 gobs of literature. There are a handful of key studies that
25 need to be discussed. And it's not something that's so far

1 gone that will distract the jury.

2 The first question the jury will have, Your Honor,
3 is, well, we know that carcinogens are out there in the world
4 and all of these places. You know, how much is it? How
5 dangerous is it? That's going to be going through their mind,
6 and we should not be prevented from discussing that with our
7 experts.

8 MR. SLATER: And that all makes sense for a personal
9 injury case where someone's claiming they got cancer from the
10 pills.

11 The decision that the FDA made was a regulatory
12 decision based on regulatory rules that said if these
13 substances -- when these substances were found, this is an
14 unacceptable risk and it's off the market and it can't be sold.
15 The recall was not medically based in the sense of there are
16 people getting cancer today. It was a regulatory
17 determination.

18 There is absolutely no way to do what counsel just
19 suggested. And Judge Kugler's statements were made very early
20 in the litigation before any issues were developed. He more
21 recently talked about the fact -- and I can't put my finger on
22 it right now, I'm sure somebody could if necessary -- where he
23 made an observation that the regulatory issues are not
24 causation issues and not -- and not medical issues because
25 they're not. There is no way to compartmentalize this.

1 If general causation comes into this trial, it's
2 going to be a few more weeks of testimony. It's going to be
3 multiple experts. It's going to be a lot more testimony. I
4 can tell you, we're holding back a huge number of designation
5 disputes just waiting for your ruling whether or not general
6 causation is in or out.

7 And, again, the FDA did not make a determination that
8 there was some medical, actual people getting cancer. That's
9 something that goes to the personal injury cases. They
10 eventually gave an analysis of how often it would happen. But
11 that is not the issue in this case.

12 CHIEF JUDGE BUMB: Why is the issue being framed as
13 one of causation? Why isn't the issue being framed as: Does
14 the presence of this NDMA make the drug worthless?

15 MS. LOCKARD: It --

16 MR. SLATER: Well --

17 CHIEF JUDGE BUMB: Another way of asking it is: Does
18 a small dosage of NDMA present an unacceptable risk? Isn't
19 that really the question? It doesn't have to go into whether
20 it causes cancer or --

21 MR. SLATER: No. I'm sorry. Didn't mean to cut you
22 off.

23 CHIEF JUDGE BUMB: I mean, why does it have to then
24 go into which is the next step of causation? Why?

25 MR. SLATER: Because it is -- that is the next step

1 of causation. And it's not an element of any of our claims.
2 Nobody's claiming a physical injury in this case. We don't
3 have to prove it.

4 CHIEF JUDGE BUMB: I understand that.

5 MR. SLATER: And therefore when they say it's not
6 enough to cause cancer, we have to try the issue in full.

7 CHIEF JUDGE BUMB: I don't think that that is the
8 relevant question, whether it causes cancer or not.

9 MR. SLATER: I agree.

10 CHIEF JUDGE BUMB: It's whether or not the presence
11 of this carcinogen is enough to -- is enough to present a risk.
12 Not whether it causes it, but is enough to present an
13 unacceptable risk. Not whether it causes it or not. But is it
14 really a risk worth taking?

15 So, you know, the way I think of it is -- you know, I
16 know it's not an FDA, it must be the Consumer Protection
17 Bureau, whatever, whoever. If -- I mean, if they take a -- it
18 used to be the chocolate eggs with the toy inside.

19 MS. ALLON: Kinder Eggs.

20 CHIEF JUDGE BUMB: Kinder Eggs. I actually tried
21 that patent case.

22 But if they take that and say, you know, you can't do
23 it because it presents a choking hazard, well, okay, are you
24 going to stand up and say, well, it still has value because
25 there's chocolate there? You're just not going to sell it.

1 We're certainly not going to wait for some child to choke.

2 But -- so it's not whether it causes someone to choke. It's
3 whether or not there's unacceptable risk.

4 And so that really should be the focus of the case,
5 which is, do the studies show that there is a risk, not whether
6 it causes it, but there's a risk.

7 MS. LOCKARD: Well, and that is, I think, a way that
8 could be presented. It's not -- we're not asking whether it
9 actually caused cancer in anyone. But we do have to quantify
10 the risk in a way.

11 I mean, the worthlessness piece of it is, it is the
12 safety profile of the drug. And, you know, in order for us to
13 be able to talk about whether the drug is safe, is it
14 effective, was it worth anything, would anybody pay money for
15 this, did anybody pay money for this, you have to look at those
16 issues related around the risk of cancer.

17 The alternative is if they just want to say --

18 CHIEF JUDGE BUMB: No, I don't think so. Sorry to
19 interrupt. But I don't think so. I think that if the studies
20 show that you shouldn't have any of this present, then you
21 shouldn't. If there's studies that show, well, it's okay if
22 you have just, you know, a minimum, whatever, a trace,
23 whatever, then it's okay. That's -- that's the case. Not
24 whether or not, well, if you do have this, it's going to cause
25 cancer, it might cause cancer. It's either what the studies

1 show. The studies show you shouldn't have any or the studies
2 show it's okay to have just a little. That's what it is. Not
3 whether or not if you have just a little whether it causes it
4 or not. That's -- now we're getting into an area where we
5 shouldn't be getting into.

6 So I think we have to limit what goes before the
7 jury.

8 MR. SLATER: And I --

9 CHIEF JUDGE BUMB: What do the studies show? What do
10 the experts say? Well, you really shouldn't have any, or it's
11 okay to have, you know, a little. That's it.

12 MR. SLATER: Well, from a regulatory standpoint,
13 which is what governs this case, because it's a regulatory
14 determination, so Your Honor knows, before this was known,
15 before it was disclosed that these pills were contaminated with
16 NDMA, nothing was allowed in. There was no rule that allowed
17 any of this to be in the pills.

18 After the fact, the FDA analyzed and came up with
19 levels, and they said these are the levels. You can have less
20 than this, but you can't have more. Every pill sold that's at
21 issue in this trial exceeded the levels that the FDA came up
22 with.

23 CHIEF JUDGE BUMB: Okay. That proves my point.

24 Plaintiffs want to say that there should be none.
25 The FDA, and I understand later, but let's say that they had

1 done it earlier, says, well, these levels are acceptable.

2 MR. SLATER: We'll live with the FDA levels, because
3 all their pills exceeded the FDA levels.

4 CHIEF JUDGE BUMB: Okay. Then we're getting into an
5 area where I don't think we should be going.

6 MR. SLATER: This is where it takes us. That's why
7 it should be out.

8 MS. LOCKARD: The issue is that the FDA levels were a
9 conservative determination by the FDA early in the process when
10 this was first learned about. There has been subsequent
11 studies, including the studies that Mr. Slater is talking
12 about, including the ones that we've cited to, Pottegard,
13 Mansouri, that suggest that the levels that the FDA set are
14 most likely higher than the reality of the risk. That's all we
15 want to be able to discuss.

16 And so it is important that we get into those studies
17 and that the jury understand what do they show about relative
18 risk. The alternative is that if they want to just be able to
19 say, well, the drug --

20 CHIEF JUDGE BUMB: You can present studies that say
21 that small doses don't present an unacceptable risk. But you
22 cannot talk about: Because it causes cancer, et cetera.
23 Because that's not necessary to this case.

24 You could present evidence that says there should be
25 no contaminants, period. You can present evidence that says

1 it's okay to have, you know, a trace or whatever percentage it
2 is, period. But you can't go into: And the reason why it's
3 okay is because they don't find that it causes cancer,
4 whatever, no. That's not in the case.

5 MR. SLATER: So we're limited to the regulatory
6 standards and argument about those?

7 CHIEF JUDGE BUMB: Or what the literature shows, I
8 suppose.

9 MS. LOCKARD: And I would also --

10 MR. SLATER: Well, that's going to become the cancer.

11 CHIEF JUDGE BUMB: No, it's not. No, it is not.

12 MS. LOCKARD: And plaintiffs --

13 CHIEF JUDGE BUMB: We're not going that far.

14 MR. HONIK: Your Honor, may I offer one thing on
15 this?

16 I think we may be losing the forest through the trees
17 in some important respect.

18 There is no place for risk analysis in a warranty
19 case.

20 CHIEF JUDGE BUMB: I know.

21 MR. HONIK: This is an economic -- if I may. What
22 our economic expert has said is really a very simple
23 proposition. And Judge Kugler has written about this
24 innumerable times in the case, not at the very beginning, but
25 once he became acquainted with it.

1 It is an immutable fact, and all the defendants
2 agree, all the experts agree, even on the defense side, that
3 you can't knowingly sell an adulterated drug. If it's true
4 that this drug is adulterated, it means from an economic
5 perspective that there's no market for it and therefore no
6 value.

7 And there are legion of cases in the federal courts
8 and other courts that have said drugs that meet that legal
9 definition, regardless of the extent of risk, little risk, big
10 risk, it doesn't matter. You can't sell it. And if that's an
11 immutable economic reality, it means that economically it's
12 zero. The damages is the delta between zero and what it was
13 sold. That's what this case is about.

14 When we get to the personal injury track, to be
15 short, causation, level of dose, amount of risk is relevant.
16 But respectfully, in a warranty case for economic losses, which
17 is what we're talking about here, there is no place for risk.
18 And respectfully, I think it's a slippery slope.

19 CHIEF JUDGE BUMB: Well, I think --

20 MR. HONIK: Once we let the defendants go there, it
21 completely takes the jury to a place that isn't a lawful
22 consideration in determining whether there's been a benefit of
23 the bargain.

24 CHIEF JUDGE BUMB: All I'm saying, I think we're all
25 saying sort of the same thing, otherwise it's just a strict

1 liability. I mean, then the plaintiffs stand up and say, well,
2 it's in there, it's other -- that's it. It's worthless.

3 Why aren't they permitted to say, well, it doesn't
4 make it worthless if there's, you know, the teeniest of
5 contaminant inside it? The plaintiffs say, no, it does make it
6 worthless because it has no value because that's what the
7 guidelines -- the regulatory guidelines say.

8 MR. SLATER: And I can also add, Your Honor, I know
9 for a fact ZHP's witnesses all admitted: If they knew about
10 it, they never would have sold it. And they say as soon as we
11 learned about the contamination, we realized we had to stop
12 selling it. It could not be sold.

13 CHIEF JUDGE BUMB: Right.

14 MR. SLATER: And it would be unethical.

15 CHIEF JUDGE BUMB: Which is why I think we are
16 arguing over something that I don't think we need to be arguing
17 about, because it seems to me that once it was known that NDMA
18 was present, everyone agreed you couldn't sell it.

19 Now, the argument is going to be, well, what about
20 pre-recall, were they entirely worthless? And I think for the
21 plaintiff to say, yes, they were because they contained the
22 contaminant, the plaintiff can argue that.

23 The defendants can say, there's literature out there
24 that would say that, you know, if it's just, you know, a
25 smallest of percentage, it's -- it's still acceptable, it's not

1 worthless, then they can do that. But it can't delve into
2 "because it doesn't cause cancer or the risk of cancer." You
3 can't delve into that.

4 MR. SLATER: Okay.

5 MS. LOCKARD: And at the same time, we would ask that
6 plaintiffs not make arguments in opening statement or with
7 their witnesses to say "this drug caused cancer." "This was a
8 cancer-causing medication," all of those types of discussion
9 points that we heard time and time again through this, because
10 that just opens the door.

11 We can't be left with that kind of rhetoric at the
12 opening and us not be able to present our defense to that.

13 If we can't say it doesn't cause cancer, they can't
14 say it does.

15 CHIEF JUDGE BUMB: It's a carcinogen that rendered
16 the drug worthless. It's a carcinogen that did not render the
17 drug worthless because there was -- it didn't pose an
18 unacceptable risk.

19 Where's the literature?

20 MR. SLATER: And I can assure Your Honor that all we
21 intend to say in opening, and counsel was concerned about, is
22 to use the same labels that they used in describing their own
23 pills and the labels that were used by the FDA regulatory, that
24 language. Genotoxic, probable human carcinogen, those are the
25 reasons they were pulled off the market. We're not going to

1 say it caused cancer. We're not going to say a bunch of people
2 got cancer. We're not planning to go there at all. We
3 understand your ruling. We're not going to suggest that.
4 We're not going to say there's people all over the country
5 getting cancer from this. That's not going to happen because
6 we understand the flip side would also apply; that they're not
7 going to say on the defense side it wouldn't cause cancer, it
8 didn't cause cancer. We understand that.

9 CHIEF JUDGE BUMB: Question?

10 MS. LOCKARD: I don't think so. I think we have an
11 agreement, an understanding. But if to some extent it's
12 unclear when we get ready or they open the door, we may be back
13 with Your Honor on this issue, so...

14 MR. SLATER: Thank you for wrestling through that.

15 CHIEF JUDGE BUMB: And I'm sure -- well, we'll see
16 what your evidence is, but -- we'll see.

17 MS. LOCKARD: Well, I mean, to be clear, if we are
18 presenting the literature and Your Honor has said that we are
19 entitled to present the literature on this issue --

20 CHIEF JUDGE BUMB: Give me a preview of the
21 literature.

22 MS. LOCKARD: Well, our expert, we will have an
23 expert who comes into court, most likely --

24 CHIEF JUDGE BUMB: Which expert is this?

25 MS. LOCKARD: Most likely Lewis Chodosh --

1 CHIEF JUDGE BUMB: Okay.

2 MS. LOCKARD: -- who will talk about the literature
3 with respect to both the valsartan pill itself and the doses of
4 NDMA that it takes to actually create a risk of cancer.

5 The issue -- the disconnect in this case is that they
6 are focused on NDMA causes cancer, NDMA is a carcinogen.

7 Our position is that it's the medication that is at
8 issue. That's the product at issue here. We're not trying a
9 case about NDMA. We're trying a case about valsartan. And so
10 in order to discuss the safety profile of that, to bring in the
11 literature that you've discussed, we will need to present an
12 expert who will talk about that literature. I mean, we can't
13 just introduce it, you know --

14 CHIEF JUDGE BUMB: About the literature, but not
15 about whether or not it causes cancer.

16 MS. LOCKARD: Okay. Understood.

17 CHIEF JUDGE BUMB: Okay. Next motion. Are we at 10?

18 MR. SLATER: Yes, Your Honor.

19 Number 10 --

20 CHIEF JUDGE BUMB: If it gets to a point where you
21 can -- all right. Go ahead.

22 MR. SLATER: I'm sorry, Judge.

23 CHIEF JUDGE BUMB: No. If there's some that we've
24 worked out as a result of what's been discussed, then tell me.
25 Okay.

1 MR. SLATER: Will do, Your Honor.

2 CHIEF JUDGE BUMB: What's 10?

3 MR. SLATER: This ones stands on its own.

4 Basically, we're seeking to preclude any reference to
5 this company called Valisure that submitted a citizen petition
6 to the FDA. There was motion practice with Judge Vanaskie
7 where the defense wanted to subpoena the records, because
8 Valisure in what they submitted, there was a reading of it that
9 suggested that they found NDMA in the reference-listed drug,
10 the brand drug Diovan. And one of the -- some of the samples
11 blinded had been sent to one of our experts, Dr. Najafi.

12 The bottom line is, the subpoena was quashed. The
13 lab --

14 CHIEF JUDGE BUMB: Okay. That doesn't come in. We
15 all agree?

16 MR. SLATER: Thank you.

17 MS. ROSE: Sorry, Your Honor. I just want to be
18 heard. These are two very different issues.

19 The Valisure subpoena is highly relevant.
20 Plaintiffs' claim is that valsartan is adulterated because it's
21 different from the reference-listed drug, Diovan, and that it
22 includes NDMA and Diovan does not. Valisure is an independent
23 laboratory. They tested a bunch of different valsartan
24 products, including products manufactured by the manufacturer
25 of Diovan, and found NDMA in it.

1 And a really interesting point that Mr. Slater just
2 kind of glossed over is that Valisure sent its results to one
3 of plaintiffs' experts, Dr. Najafi, and asked for his
4 validation. And the samples he got, he validated that
5 Valisure's results were right.

6 So if Valisure indicates that there was NDMA in
7 Diovan, the reference-listed drug, then plaintiffs' theory that
8 valsartan is automatically adulterated because there's NDMA in
9 it and not in the reference-listed drug, then that's a serious
10 problem. And Judge Vanaskie has heard all about this because
11 we were seeking additional discovery from Valisure to figure
12 out exactly what samples they had tested to get more
13 information on this for trial.

14 And Judge Vanaskie and I believe Judge Kugler as well
15 both held this is highly relevant, highly relevant information,
16 undermines plaintiffs' claims, but it was with the ruling for
17 why the subpoena was quashed was because it was late. Their
18 discovery had closed and Your Honor spoke about earlier, it was
19 just too late. They weren't going to issue the subpoena.

20 But there was no finding that Valisure was
21 irrelevant. There was no finding that it was unreliable. To
22 the contrary, both Judge Vanaskie and I believe Judge Kugler
23 said the fact that defendants realized the importance of
24 Valisure too late is unfortunate, but we're going to -- we're
25 past the discovery period. So it is relevant evidence. So

1 this is -- the quashing of the subpoena has really nothing to
2 do with whether this is admissible at trial.

3 CHIEF JUDGE BUMB: What do you want to introduce?

4 MS. ROSE: We would like to introduce the fact that
5 Valisure, an independent laboratory, submitted a citizens
6 petition to the FDA stating that it found NDMA in a variety of
7 valsartan drugs, including valsartan drugs that were
8 manufactured by the manufacturer of Diovan. And the
9 manufacturer of Diovan only sold Diovan -- only sold valsartan
10 that was labeled/branded Diovan in the United States.

11 So the samples that it found NDMA in it, it follows
12 that those samples were Diovan samples.

13 MR. SLATER: Okay. There's an incredible amount of
14 supposition there that was never tied up. There's --

15 CHIEF JUDGE BUMB: Wait one second. Who would you
16 call?

17 MS. ROSE: I'm sorry?

18 CHIEF JUDGE BUMB: Which -- who -- what witness would
19 you call?

20 MS. ROSE: Our expert, Ali Afnan, discusses the
21 Valisure petition which was sent to the FDA, a citizen's
22 petition to the FDA.

23 CHIEF JUDGE BUMB: Right. He didn't do the analysis?

24 MS. ROSE: No. Dr. Najafi, one of plaintiffs'
25 experts, he validated the Valisure decision. So plaintiffs are

1 now saying, oh, Valisure is irrelevant, Valisure has nothing to
2 do with this, it's unreliable. But their own expert validated
3 some of the Valisure results.

4 CHIEF JUDGE BUMB: So they're going to call their own
5 expert and you'll have it -- you'll get it in through them.

6 MS. ROSE: Yeah. We'd like to cross-examine their
7 expert, Dr. Najafi, about this.

8 MR. SLATER: Except that's not what happened.
9 Dr. Najafi never was able to confirm that he did, in fact, test
10 a Diovan sample. He had blinded samples. Valisure couldn't
11 show it.

12 More important, Health Canada, by the way, tested
13 Diovan and found no NDMA.

14 CHIEF JUDGE BUMB: Okay. So let me just cut to the
15 chase. There's no direct evidence of who did this. I mean,
16 this is through a citizen's petition, so it's so many different
17 layers removed. It's not going to come in through the
18 petition. It's a citizen's petition. It doesn't even talk
19 about who did the analysis.

20 If your expert did the analysis independently, that's
21 permissible ground for them to cross on. But other than that,
22 it's not going to come in. It's too many layers removed.

23 Okay. 11.

24 MS. ROSE: Your Honor, sorry, just to clarify. Can
25 we cross-examine Dr. Najafi on the fact that he validated some

1 of Valisure's --

2 CHIEF JUDGE BUMB: Yes.

3 MR. NIGH: Your Honor, that deposition --

4 CHIEF JUDGE BUMB: Yes.

5 MR. SLATER: I don't want to cut you off. But to be
6 very clear, there's a very important issue here. What is
7 Valisure? Like, Valisure is some independent entity --

8 CHIEF JUDGE BUMB: That's why it's not coming in.

9 MR. SLATER: But they want to inject it by
10 cross-examining Dr. Najafi to inject the issue into the case,
11 and then he's going to say I don't -- I didn't test the Diovan
12 samples, to my knowledge.

13 CHIEF JUDGE BUMB: Then that's one question asked and
14 one question answered, and then we move on. We're not -- it's
15 not going to -- we're not going to delve into Valisure, we're
16 just not.

17 MR. SLATER: Okay. Because --

18 CHIEF JUDGE BUMB: It's -- that's another trial
19 within a trial.

20 MR. SLATER: We have no doubt it was ever done on the
21 lab. And actually, the FDA on December 5 --

22 CHIEF JUDGE BUMB: I just ruled that unless someone
23 who did the analysis is coming in to testify, it's not coming
24 in.

25 MR. SLATER: Thank you.

1 CHIEF JUDGE BUMB: They are permitted to ask your
2 expert did he do an independent analysis of the Diovan. And if
3 he did, he did. If he didn't, he didn't. They're permitted
4 to --

5 MR. SLATER: His answer would be, I think, "I don't
6 know," because he looked at blinded samples. And nobody knows
7 what they match up to.

8 CHIEF JUDGE BUMB: Well, then, it's a question asked
9 and answered. Okay. Then we move on.

10 What's your next motion?

11 MR. SLATER: The next motion has to do with an
12 argument the defense wants to make that because the compendial
13 specifications for these drugs did not explicitly say you can't
14 have NDMA in them, that they were not -- that the
15 specifications allowed NDMA, or the flip side, did not preclude
16 NDMA, as if every single toxic or dangerous substance on Earth
17 would need to be listed to show it's prohibited. The
18 compendial standards list what's allowed to be in the drug,
19 what impurities are allowed, at what levels.

20 NDMA was never permitted, was never allowed. But the
21 defense wants to say, well, it wasn't listed as not being
22 allowed so therefore it is allowed. And we believe that that,
23 again, would be a waste of time and very confusing and
24 misleading to a jury to have to hear that.

25 MR. HARKINS: Your Honor, the compendial

1 specifications for these drugs are not disputed. They provide
2 tests for certain materials. They also provide a test and a
3 specific threshold for unknown and unidentified impurities.

4 We will argue that that is the specification and the
5 threshold that would, if the level of NDMA had exceeded it,
6 triggered an investigation or enabled the defendants to
7 identify this earlier.

8 The specifications themselves are simply silent on
9 NDMA or any other nitrosamine because they were not known or
10 expected to be present in these types of drugs.

11 We will present the evidence that those
12 specifications, as listed in the FDA-approved ANDAs, were met.
13 And we understand that plaintiffs are going to argue that
14 something else should have either been included or done. But
15 the fact of what those improved specifications were and whether
16 the testing that was performed on the drugs met those
17 specifications, met every single specification listed in there,
18 is something that we will intend to introduce.

19 MR. SLATER: The specifications also did not preclude
20 arsenic, plutonium, or any of about a million other things that
21 can kill you. So the argument is disingenuous and it would be
22 misleading to the jury.

23 CHIEF JUDGE BUMB: I will allow it in very limited.
24 That will be your cross-examination or your second question.
25 And I think you've made your point.

1 You know, I sit up here and really, sometimes I -- I
2 mean, not sometimes, I'm just asking myself, are these
3 arguments really going to be being made to the jury? But I
4 guess they are.

5 Okay. Twelve.

6 MR. SLATER: It's basically the same motion having to
7 do with the USP monograph. It's the same issue.

8 CHIEF JUDGE BUMB: Okay. Same ruling.

9 MR. SLATER: The next one is we --

10 CHIEF JUDGE BUMB: I take it there's no USP monograph
11 for arsenic?

12 MR. SLATER: Well, there's a -- I don't know the
13 answer to that. The USP monograph where it lists the
14 impurities that are known that are actually in the substance,
15 they tell the levels that would be permitted. So what I'm
16 saying is, it doesn't list impurities that are prohibited such
17 as arsenic or any other thing.

18 CHIEF JUDGE BUMB: Yeah. Right.

19 MR. SLATER: That's all I'm saying. I have -- the
20 monographs are for permitted regulated drugs that the FDA
21 allows to be sold.

22 CHIEF JUDGE BUMB: Okay. "All drugs have
23 impurities." Do you have an expert that's going to say that?

24 MS. ALLON: Yes. Yes, Your Honor. It is a
25 scientific fact that all drugs have impurities. The plaintiffs

1 actually don't dispute that. This goes to the issue of the
2 monograph, right? We're going to talk about the monograph
3 tells you what to test for and what the acceptable levels are.

4 In order for the jury to have context for what a
5 monograph is, they have to know that, yes, all drugs have
6 impurities, and the monograph tells you what to look for and
7 how much of it can be in the drug. That is critical context.

8 CHIEF JUDGE BUMB: Okay. All right. Okay. You can
9 do it.

10 Fourteen.

11 MR. SLATER: This is hopefully a simple one that
12 because everybody has admitted that every one of the pills at
13 issue was contaminated, that the defense should not talk about
14 the alleged presence of these impurities; that it's purported
15 impurities; anything that casts doubt on whether these were
16 actually contaminated with NDMA.

17 CHIEF JUDGE BUMB: Okay. Do you all agree that they
18 all were contaminated?

19 MR. KASPARIE: We're not arguing that they don't
20 contain nitrosamines. I think we just don't want to be
21 precluded from arguing that the amount that was in there, as we
22 talked about earlier, is something that will cause cancer or
23 that makes the drugs worthless. We just want to be allowed to
24 argue --

25 CHIEF JUDGE BUMB: You have to reframe the issue that

1 they pose an unacceptable risk.

2 MR. KASPARIE: Sorry. Unacceptable risk.

3 CHIEF JUDGE BUMB: Okay. All right. So they're not
4 going to say that.

5 Okay. Fifteen.

6 MR. SLATER: Because none of the defendants have
7 experts against one another, because none of the defendants
8 filed cross-claims against one another for contribution or
9 indemnification, they should not be permitted to blame one
10 another.

11 MR. OSTFELD: Your Honor, it's a three-sentence
12 motion unsupported by authority. We're not planning to go into
13 court and finger point at each other. But I do think the point
14 needs to be made, the defendants have to be allowed to
15 distinguish themselves from one another. We --

16 CHIEF JUDGE BUMB: Yeah. But you're not -- there's
17 no -- well, yeah. I mean, they can do that.

18 MR. SLATER: Of course they can defend themselves,
19 but they can't blame one another, including if one of them
20 settles at some point, they can't point the finger at the empty
21 chair, because they have no experts against one another, and
22 they never filed cross-claims for indemnification or
23 contribution against one another. So we just wanted to make
24 that clear from the very beginning that if somebody settles,
25 nobody can point the finger at that chair, because they don't

1 have the expert to do it or the cross-claim to do it.

2 CHIEF JUDGE BUMB: That's true.

3 MR. OSTFELD: Your Honor, I guess I'm struggling with
4 the word "blame" a little bit, because I think it's fine for
5 Teva to say we didn't know something that ZHP knew. I think
6 it's fine for Torrent to say we didn't know something that ZHP
7 at least allegedly knew. You know, there are emails that were
8 written within ZHP that we never had access to. That's not
9 blaming. It is differentiating. I think we have to be allowed
10 to make that argument.

11 CHIEF JUDGE BUMB: Yeah. I agree.

12 Okay. Sixteen.

13 MR. STANOCH: I will give Mr. Slater a break, Your
14 Honor, if that's okay.

15 CHIEF JUDGE BUMB: We'll take a break in a couple
16 minutes, yeah.

17 MR. STANOCH: Judge, this one is about defendants not
18 being able to assert argument about the cost of replacement
19 drugs or therapies.

20 CHIEF JUDGE BUMB: Okay.

21 MR. STANOCH: You have to understand, this benefit of
22 the bargain theory we're alleging, and Your Honor touched on
23 this earlier today, right now after lunch, what's the value of
24 what TPP's consumers actually received, right? Zero,
25 something, as defendants say, greater than zero potentially.

1 CHIEF JUDGE BUMB: Uh-huh.

2 MR. STANOCH: They want to go beyond that, right?

3 This is beyond the efficacy and safety of the drug or whether
4 it was worthless. They want to say, well, if you knew about
5 the contamination earlier, you would have had to buy a
6 different drug, maybe noncontaminated valsartan, maybe a brand
7 name drug, maybe you would have had a diet regimen or something
8 like that that could help control your hypertension, and that
9 would have had a cost to it, and that cost should offset your
10 damages.

11 There's no --

12 CHIEF JUDGE BUMB: But isn't it just relevant what
13 you paid? That's it, period.

14 MR. STANOCH: I agree.

15 CHIEF JUDGE BUMB: Okay.

16 MR. STANOCH: Right. They paid \$10, what are the
17 damages? Something between zero and \$10, right? That's what
18 we're talking about. It doesn't -- no one comes in -- if I
19 bought a ladder with a broken step at Home Depot, right, my
20 damages are not extinguished by Home Depot saying, well, if you
21 would have bought a ladder that was not broken, then you would
22 have paid the same amount of money, therefore, you have no
23 damages. That's what they're trying to say. They're trying to
24 say you paid \$5 for valsartan. Okay. Well, you would have
25 paid \$5 for noncontaminated valsartan. You might have paid \$6

1 for, you know, Janumet or some other drug, therefore, that's an
2 offset to your damages. That's not the way recovery works.
3 That's not the way the benefit of the bargain works.

4 CHIEF JUDGE BUMB: Okay. Let me hear from your
5 adversary.

6 MS. ALLON: Your Honor, the plaintiffs cite no case
7 law for that proposition. We cite case law, the *Celexa* case,
8 the *Namenda* case, that explains that the measure of damages has
9 to consider what the plaintiff paid for the drug and the cost
10 of an alternative treatment. Because in the but-for world the
11 plaintiffs have constructed, we do the recall earlier. Okay.
12 In that situation, the insureds don't have access to our
13 products, but they don't just not treat their hypertension.
14 They buy something else. And so the cost of that replacement
15 medication is relevant to the measure of damages.

16 CHIEF JUDGE BUMB: Did you folks do discovery on
17 this?

18 MS. ALLON: Your Honor, our expert -- we didn't need
19 discovery because our expert, Dr. Stiroh, looked at the cost of
20 replacement medications during that time period and does an
21 analysis of them.

22 We also have admissions from the plaintiffs that they
23 would have had to take alternative medicine, and so, yes, we
24 have a body of evidence. So actually, I should revise, yes, we
25 did take discovery on this issue. And our testimony about the

1 cost of replacement, I think they say it's speculative. It's
2 not speculative. It will be founded in the record in
3 admissions from the plaintiffs and an economic analysis that
4 Dr. Stiroh has done.

5 MR. STANOCH: Judge, this is not a case about
6 comparable value. This is not an antitrust pay-for-delay case
7 where you do, as a measure of damages, measure, right, the cost
8 differential between the brand of drug and the alternative
9 drug. This is about what you actually got and what the value
10 is of what you actually received.

11 There's no evidence -- I disagree that there's
12 evidence in the record about other drugs. Years ago we sought
13 discovery, Your Honor, about other drugs. And the defendants
14 vociferously opposed it, saying that's beyond the scope and,
15 quote, other drugs discovery was denied. And now they want to
16 come in with an expert who has -- there's no evidentiary basis
17 of fact about --

18 CHIEF JUDGE BUMB: Who's the expert?

19 MS. ALLON: It's Dr. Stiroh, Your Honor. And we cite
20 to this in our motion. She does an analysis of the actual
21 prices of replacement drugs. Again, there's no need for
22 discovery. The prices are a matter of public record. She
23 relied on them in her report. They weren't excluded by the
24 Court.

25 In fact, Judge Kugler recognized that this

1 disagreement, he said in his class cert order, points straight
2 to a central trial issue. What economic loss damages do
3 defendants owe plaintiffs?

4 Their economic loss is limited to the delta between
5 what they did pay in the real world and what they would have
6 still had to have paid in the but-for world for alternative
7 medication. That is absolutely the measure of damages in this
8 case.

9 And, again, the plaintiffs themselves admitted that
10 they would have had to pay for other hypertension drugs. They
11 were not just going to let their members go untreated for
12 hypertension.

13 MR. STANOCH: Your Honor, Dr. Stiroh at the class
14 certification, her report was more limited. There is a pending
15 *Daubert* -- Rule 702 motion fully as to Dr. Stiroh now on this
16 counter-factual but-for world that she's trying to construct in
17 a world of --

18 CHIEF JUDGE BUMB: There's no ruling on her?

19 MR. STANOCH: There is no ruling on Dr. Stiroh's --
20 our *Daubert* motion as to Dr. Stiroh's liability report,
21 correct.

22 MS. ALLON: There was a ruling on the same issue at
23 class certification. That's when Judge Kugler made the comment
24 that I referred to.

25 CHIEF JUDGE BUMB: What *Dauberts* are you owed?

1 MR. STANOCH: We are owed, I believe, three *Daubert*
2 motions. I could be wrong. There is plaintiffs' *Daubert*
3 motion as to defense experts Gibson and Stiroh.

4 CHIEF JUDGE BUMB: Okay.

5 MR. STANOCH: And there is the defense --

6 CHIEF JUDGE BUMB: Stiroh is the one that you're
7 discussing now.

8 MS. ALLON: Yes, Your Honor.

9 CHIEF JUDGE BUMB: Yeah.

10 MR. STANOCH: And there is the defense 702 motion as
11 to our damages expert, Dr. Rena Conti.

12 CHIEF JUDGE BUMB: Okay.

13 MS. ALLON: But this is a live issue regardless of
14 the Rule 702 motion, right? Let's just assume Dr. Stiroh --

15 CHIEF JUDGE BUMB: I know. Here's what I'm going to
16 say: All pending *Daubert* motions, I'm holding the hearings.
17 So you folks will have to talk to me about dates for the
18 *Daubert* hearings. We'll do them sooner than later. I want
19 further briefing on this issue. I don't find the briefing to
20 be sufficient. I want further briefing on the issue. And I'm
21 reserving.

22 And I want, Mr. Stanoch, you said something
23 interesting about, well, you wanted discovery on this and you
24 were denied it. So that's going to be important for me to hear
25 about that, too.

1 MR. STANOCH: Yes, Your Honor.

2 CHIEF JUDGE BUMB: So I'm going to reserve on 16.

3 MR. STANOCH: Thank you, Judge.

4 CHIEF JUDGE BUMB: Okay. Let's take a five-minute
5 break, and I'll be back, and we'll pick up with 17, okay?

6 (Recess was taken at 3:36 p.m. until 3:57 p.m.)

7 THE COURTROOM DEPUTY: All rise.

8 CHIEF JUDGE BUMB: Okay. You can have a seat. Thank
9 you.

10 MS. DAVIDSON: Your Honor.

11 CHIEF JUDGE BUMB: Yeah.

12 MS. DAVIDSON: Before we continue, can I ask you a
13 question; I've been nominated.

14 There's a lot of people in here who want to know if
15 they should move their flights and around the time you're
16 planning to go to today.

17 CHIEF JUDGE BUMB: Till we finish.

18 MS. DAVIDSON: Okay.

19 CHIEF JUDGE BUMB: So the more you agree on, the
20 better we are.

21 (Laughter.)

22 CHIEF JUDGE BUMB: I want to get through all these
23 motions in limine. I want to set the trial date. I just want
24 to get this done, and I want to set the *Daubert* hearing. Okay.
25 So we'll go fast.

1 Seventeen is moot. We already talked about that,
2 right?

3 Eighteen. Defendants can't rely on opinions of
4 defense experts. That relying on precluded -- well, that's
5 kind of obvious.

6 And Dr. Afnan I'm bringing in, so we'll see how that
7 goes.

8 Defendants cannot argue that the relevant warranties
9 only went to the prescribers. What does that mean, 19?

10 MR. SLATER: This is sort of an add-on to the motion
11 before about we're not going to blame the doctors. Sort of our
12 understanding, we negotiated a lot of these things, and the
13 defense would not agree not to make arguments that the
14 information was going to doctors and the doctors are the
15 relevant recipients, where this is not a product liability case
16 with a learned intermediary doctrine.

17 CHIEF JUDGE BUMB: Okay.

18 MR. SLATER: It's a warranty case having to do
19 with --

20 CHIEF JUDGE BUMB: Right. I agree.

21 Twenty. Defendants can't argue they are good
22 companies.

23 Why not? They can argue whatever they want. The
24 evidence may be to the contrary.

25 MR. SLATER: Because then we would be potentially

1 putting in the counter to that, and I thought this was
2 potentially going to be agreed to. But --

3 CHIEF JUDGE BUMB: You guys agree to this? Yes? You
4 all agree?

5 MS. ROSE: Well, Your Honor, the motion as written is
6 very overbroad and I think that was our issue. Plaintiffs have
7 punitive damages in this case. They're obviously going to make
8 claims about ZHP and other defendants putting profits over
9 safety, and we have the ability to contest that and to discuss
10 the role of the -- the role of the companies, what they do.

11 Also, as witnesses, it's just very overbroad as it's
12 written that our witnesses wouldn't be able to explain what
13 they do in the context of their jobs, if it's something that is
14 positive or something that is viewed as having a benefit to
15 society. We just think it's just too broad. This is just
16 hamstringing us from providing evidence.

17 MR. SLATER: There's just no relevance to either side
18 talking about you're generally good or you're generally bad.
19 It's what did they do here.

20 CHIEF JUDGE BUMB: Well, I don't anticipate that
21 they're going to get up and take the stand and say, "Hi, I'm
22 from a good company."

23 MR. SLATER: I think it's going to be close. There's
24 another motion about we make lifesaving drugs, we help people
25 all over the world, this is a life --

1 CHIEF JUDGE BUMB: They can -- I mean, they can say
2 that with a -- okay. They can toot their own horn for a couple
3 of minutes. Why not?

4 MR. SLATER: But I suppose that opens the door to us
5 then crossing them on, well, let's talk about the negatives
6 about your company, too, like if there's been criminal
7 investigations or other things or other issues they've had. If
8 they make general statements about being good companies, we
9 would then come in with a barrage of negative evidence.

10 CHIEF JUDGE BUMB: I will balance it. They can say
11 how great they are, but they will do it at their own peril.

12 MR. SLATER: Okay.

13 CHIEF JUDGE BUMB: They don't just free rein talk
14 about all the good.

15 Okay. 21. Defendants cannot postulate a "but-for"
16 world.

17 What does that mean?

18 MR. STANOCH: Hello again, Your Honor.

19 Essentially, this argument boils down to something
20 that was raised at class certification, but Judge Kugler
21 excluded Dr. Keller's opinions, and I don't believe she
22 submitted a liability report, so it may be largely moot but for
23 the argument.

24 Essentially the argument goes likes this: If -- if
25 the nitrosamines were disclosed earlier than the summer of

1 2018, right, maybe if people knew the truth, they would have
2 bought it anyway.

3 CHIEF JUDGE BUMB: That's speculative. You can't
4 argue about that.

5 MR. STANOCH: Thank you, Judge.

6 CHIEF JUDGE BUMB: Okay. Twenty-two.

7 MR. SLATER: This is just a straightforward motion
8 based on the law we filed; that the jury shouldn't be told
9 about exactly what we listed there: The potential treble
10 damages, attorney's fees, statutory penalties, interest, any of
11 those issues.

12 CHIEF JUDGE BUMB: Right. Okay. Granted.
13 Twenty-three.

14 MR. SLATER: This is -- this motion is intended to
15 preclude the defendants -- and, frankly, we're going to live by
16 the same rules -- from generally saying they complied with --

17 CHIEF JUDGE BUMB: Right. They can --

18 MR. SLATER: As opposed to specifying.

19 CHIEF JUDGE BUMB: That's right. They can do that.

20 MR. SLATER: They just have to specify what SOP, what
21 guidance they complied with.

22 CHIEF JUDGE BUMB: Yes. Otherwise, it has no value
23 to the jury.

24 MR. SLATER: Okay.

25 CHIEF JUDGE BUMB: Other than to say, yeah, we

1 complied.

2 MS. LOCKARD: Yeah. We have no problem with that,
3 Your Honor. And I think we're very close to an agreement on
4 this one. But we want to be able to say in opening and so
5 forth we complied with the applicable regulations, the
6 applicable specification. We will certainly get into those.
7 We don't intend to talk about any that weren't produced in
8 discovery. And if we overstate our position, they can
9 certainly bring that to the jury's attention, and I'm sure they
10 will.

11 CHIEF JUDGE BUMB: You can do that. Next.

12 MR. SLATER: This was what I just said, talking about
13 these drugs being lifesaving drugs and their importance to
14 society, et cetera.

15 That's really not relevant in a general sense. The
16 question is whether or not the contamination here rendered the
17 drugs worthless or what value.

18 CHIEF JUDGE BUMB: Right. I mean, they can -- it
19 doesn't -- they can call it a lifesaving drug if they want.
20 They kind of do it at their own peril.

21 MR. SLATER: Okay.

22 CHIEF JUDGE BUMB: I mean, it really kind of opens
23 the door for you to --

24 MR. SLATER: Understood.

25 CHIEF JUDGE BUMB: -- lifesaving drug? I mean, I

1 don't know. I don't want to tell everybody how to try their
2 case.

3 MR. SLATER: No; I understand.

4 CHIEF JUDGE BUMB: I mean, some of these arguments,
5 as I say, I scratch my head saying what? Really?

6 Okay. 25.

7 MR. SLATER: We want to preclude the defendants from
8 saying that prescription of these drugs was the standard of
9 care as opposed to say basically this is the only -- this is
10 the way to treat these conditions, because there's a whole host
11 of medications and treatments that can be used to treat high
12 blood pressure. So we don't want anybody to say on the defense
13 side that this is standard of care to give these types of
14 medications when there's a whole bunch of other different
15 medications and treatments out there.

16 To suggest to the jury that the standard of care is
17 these are the drugs you give and these are the drugs you need,
18 to elevate their importance in terms of treatment.

19 MS. BRANCATO: Your Honor, we don't intend to argue
20 that valsartan was the only drug. In fact, we are going to
21 point out that there were other drugs as part of our damages
22 theory. So I don't think this is an issue.

23 CHIEF JUDGE BUMB: Okay. So it's moot.

24 26.

25 MR. SLATER: I'm assuming from the title, it's

1 straightforward. That was just a housekeeping issue.

2 CHIEF JUDGE BUMB: Yes. No party is going to come
3 before this jury and assert any evidence or any argument that
4 is inconsistent with their stipulations.

5 Twenty-seven. We've already talked about 27, haven't
6 we?

7 MR. STANOCH: Your Honor, yes. I would --

8 CHIEF JUDGE BUMB: Didn't we talk about 27?

9 MR. STANOCH: I think we have, yes. I think this
10 dovetails with things earlier.

11 CHIEF JUDGE BUMB: Twenty-eight, defendants cannot
12 argue that they complied with cGMPs in the manufacture...

13 Well, I've already ruled on that; that that is
14 permissible. But, you know, with -- under the guidance that
15 I've given the parties. So I think that's moot, isn't it?

16 MR. SLATER: I believe you've ruled on that, Your
17 Honor.

18 CHIEF JUDGE BUMB: Yeah.

19 Twenty-nine I've ruled on; have I not?

20 MR. SLATER: Yes.

21 CHIEF JUDGE BUMB: Okay. Thirty, defendants cannot
22 argue that the contamination was unavoidable or unforeseeable.

23 MR. SLATER: My sense is, understanding what Your
24 Honor's ruling was going to be on that, that you'll most likely
25 permit them to make that argument if they choose to.

1 CHIEF JUDGE BUMB: Yeah, I think so.

2 Thirty-one.

3 We talked about this, didn't we?

4 MR. STANOCH: Yes, Your Honor. I think that's fair
5 to say.

6 CHIEF JUDGE BUMB: We've had a robust conversation
7 about these things.

8 Thirty-two. Teva and Torrent cannot argue that they
9 were not responsible for the quality into their finished-dose
10 VCDs. I think we talked about this, too. They can, to a
11 degree; can they not?

12 MS. LOCKARD: We would say so.

13 CHIEF JUDGE BUMB: I thought we talked about this.

14 MR. STANOCH: I don't know, Your Honor, if we talked
15 about it specifically. It's simply that we have heard argument
16 from certain witnesses of these two defendants that it wasn't
17 their API. It wasn't our fault. It was ZHP. And this is just
18 making clear that under the federal laws and regulations, the
19 ANDA holder, which is Teva and Torrent --

20 CHIEF JUDGE BUMB: Yeah.

21 MR. STANOCH: -- are responsible for the entirety of
22 their drug, including the API.

23 CHIEF JUDGE BUMB: Right.

24 MR. STANOCH: So they can't give the jury the
25 misimpression. They can certainly say factually ZHP made the

1 API and maybe they bear a lot of responsibility, but they can't
2 just wipe their hands and say it wasn't us, the drug substance.
3 Whether it was excipient, active pharmaceutical ingredient,
4 coating, whatever it is, it's their drug, and they can't walk
5 away from their drug. That's all.

6 CHIEF JUDGE BUMB: You agree?

7 MS. LOCKARD: I think he can make the argument and he
8 will cross-examine our witnesses about what our responsibility
9 was with respect to finished dose. We had some adequate
10 testimony on that. I'm sure I'll hear. I don't think this is
11 proper for a motion in limine to exclude us from talking about
12 what our responsibilities were or were not.

13 CHIEF JUDGE BUMB: Right. Okay. I think you both
14 said the same thing.

15 Okay. Defendants cannot raise the notice issues
16 raised on the dispositive -- I'm not sure what this means.

17 MR. SLATER: That's been decided.

18 MR. STANOCH: That's moot, Your Honor.

19 CHIEF JUDGE BUMB: It's moot.

20 MR. STANOCH: Summary judgment.

21 MR. HONIK: On the adequacy issue.

22 CHIEF JUDGE BUMB: Thirty-four, defendants cannot
23 assert irrelevant, confusing, misleading, or unduly prejudicial
24 background facts about MSP or its assignors.

25 MR. STANOCH: Yes.

1 CHIEF JUDGE BUMB: Granted.

2 MR. STANOCH: Thank you.

3 CHIEF JUDGE BUMB: No party can assert anything
4 that's irrelevant, confusing, misleading, or unduly prejudicial
5 about anybody.

6 MR. MARTIN: Your Honor, if I may for a moment.

7 CHIEF JUDGE BUMB: Yes.

8 MR. MARTIN: I completely agree, the title of the
9 motion is basically just restating Rule 403. Our trouble was
10 that what they actually asked for in the text, it's a blanket
11 order saying we can't say anything mean about MSP and we can't
12 reference that they're an assignor. We think that's way
13 overbroad for the state of the proceedings. And --

14 CHIEF JUDGE BUMB: What do you want to say about MSP
15 other than they're --

16 MR. MARTIN: I think we would cross-examine their
17 witnesses on things that are relevant to their credibility.

18 CHIEF JUDGE BUMB: What does that mean?

19 MR. MARTIN: And that includes references --
20 questions about MSP's financial condition, questions about --
21 and I think questions about them as an assignor. They do have
22 to show, putting aside the champerty argument we discussed this
23 morning, they still have to show their chain of assignments as
24 part of their prima facie case. They still have to show that
25 those assignments are valid, supported by consideration to the

1 particular subsidiary that's bringing the suit, and so forth.

2 So we don't want to be inflammatory. We don't want
3 to violate 403. But we do believe we have a right to challenge
4 the credibility of MSP witnesses, MSP documents, and MSP
5 assignors.

6 CHIEF JUDGE BUMB: You can talk about who MSP is, but
7 it's not going to be in sort of a character assassination about
8 these types of assignments are just, you know, awful and why do
9 we --

10 MR. MARTIN: Understood.

11 CHIEF JUDGE BUMB: Why as a society do we allow
12 these, and this is a terrible thing. We're not going to go
13 there.

14 MR. MARTIN: Okay. I don't think we plan to. Thank
15 you, Your Honor.

16 CHIEF JUDGE BUMB: And by the way, I read that there
17 were some issues, the assignments themselves are in dispute, or
18 there's an issue about authentication. Are we really going
19 to -- is that a problem?

20 MR. SLATER: I thought Judge Kugler already ruled
21 that the assignments had been -- were valid and that that issue
22 had been decided already.

23 CHIEF JUDGE BUMB: No. In terms of proving, is there
24 a stipulation on that? I thought I read somewhere in one of
25 the briefs.

1 MR. MARTIN: That's in one of the trial briefs, Your
2 Honor. And I think our position on that is that these are not
3 self-authenticating documents. They -- you know, the
4 assignments -- the chain of assignments are not
5 self-authenticating. And if they want to prove them, they need
6 to bring in a witness to go through that.

7 CHIEF JUDGE BUMB: And you might be right. You might
8 be right. But you folks on this side of the aisle are going to
9 have to show me why in good faith you can't stipulate to these
10 assignments.

11 MR. OSTFELD: Well, Your Honor, if I could speak to
12 that. The consideration is absent from the assignments that
13 were produced. The adequacy of the consideration is a core
14 question and whether assignments are valid. And numerous
15 lawsuits brought by MSP have been dismissed based on the
16 inadequacy of the assignment, so...

17 CHIEF JUDGE BUMB: And do you have that in discovery?

18 MR. OSTFELD: We sought to the unredacted versions of
19 the assignments which were not provided to us. And, frankly,
20 Your Honor, it is the assignor's responsibility to demonstrate
21 the validity -- the assignee's responsibility to demonstrate
22 the validity of the assignment and the validity of their
23 claims.

24 CHIEF JUDGE BUMB: So if the assignments show one
25 dollar, you're fine?

1 MR. OSTFELD: No, Your Honor. The case law is very
2 clear that a one dollar consideration is not adequate. These
3 are Florida and Delaware law-governed assignments. They have
4 to meet the standards of Florida and Delaware law. And a
5 peppercorn-style consideration does not satisfy those
6 standards. They've got to provide their consideration. If
7 they can do that, maybe we can reach a stipulation.

8 CHIEF JUDGE BUMB: What's the answer?

9 MR. STANOCH: Judge Kugler, Your Honor, already ruled
10 at the motion-to-dismiss stage that MSP had standing based on
11 these assignments. All the assignments have been produced
12 multiple times, despite Judge Vanaskie's order for any time
13 they wanted an assignment. The judge found MSP was an adequate
14 class representative based on the evidentiary record --

15 CHIEF JUDGE BUMB: But now we're talking about an
16 evidentiary issue about how you prove the assignment to the
17 jury.

18 MR. STANOCH: It was a preponderance of the evidence
19 at Rule 23 stage. And then at summary judgment and at
20 decertification they again tried to argue about the assignments
21 and there was no issue of that going forward.

22 CHIEF JUDGE BUMB: Are you saying it's res judicata;
23 that Judge Kugler already found as a matter of law that the
24 assignments are valid?

25 MR. STANOCH: I think I'd say at least the law of the

1 case, Your Honor, yes. The assignments have been litigated
2 multiple times. And what might have happened in some other
3 case one time for another MSP entity five years ago has no
4 bearing on what Judge Kugler has ruled repeatedly by making MSP
5 the presumptive lead TPP trial candidate.

6 MR. OSTFELD: Your Honor, this issue has certainly
7 not been ruled on by Judge Kugler. He's never ruled on the
8 adequacy of the consideration in these assignments. He has
9 held that MSP was an adequate class representative, but we are
10 still, the onus is on them. We're talking about a trial here.

11 CHIEF JUDGE BUMB: Why didn't you move for summary
12 judgment on this issue? Here we are.

13 MR. OSTFELD: I'm sorry, Your Honor?

14 CHIEF JUDGE BUMB: Why did you not move for summary
15 judgment on this issue? Here we are.

16 MR. OSTFELD: Your Honor, we --

17 CHIEF JUDGE BUMB: Months before trial. And if they
18 can prove that they're the proper assignee, then that's an
19 issue.

20 MR. OSTFELD: Your Honor, we have repeatedly
21 contested the adequacy of MSP. I believe we did at the summary
22 judgment stage.

23 CHIEF JUDGE BUMB: Why didn't you move for summary
24 judgment?

25 MR. OSTFELD: I don't recall if we did at summary

1 judgment or not, Your Honor. The problem is it is their burden
2 of proof. We're not --

3 CHIEF JUDGE BUMB: I know. But we're not going to
4 try the case by ambush. I want to know why you didn't move for
5 summary judgment on a very critical element.

6 MR. OSTFELD: Your Honor, I would need to review the
7 summary judgment papers. I don't recall if we have moved on
8 this or not. But I do know that it is part of their burden of
9 proof to demonstrate the adequacy of the assignment.

10 CHIEF JUDGE BUMB: I know.

11 MR. OSTFELD: I'm not talking about trial by ambush,
12 Your Honor. We have repeatedly throughout this case made clear
13 that we do not believe MSP is an adequate representative; that
14 we believe that MSP's assignments are very much at issue. We
15 sought the unredacted assignments, which they declined to
16 provide. So, Your Honor, I don't think we're the ones
17 ambushing here. We've been very clear about our intentions
18 from the start.

19 CHIEF JUDGE BUMB: It seems to me that if it is a
20 classic case of that they are not a proper plaintiff, you would
21 have filed that motion a long time ago.

22 You would have filed a motion that says there's no
23 discovery, there's no evidence in the record, therefore, grant
24 summary judgment, Judge Kugler.

25 MR. OSTFELD: We have filed innumerable motions

1 regarding MSP. We haven't prevailed on them, but none of that
2 erases the fact that we are now at the trial stage. And part
3 of the element of their claim is demonstrating that they have
4 valid assignments. They cannot proceed on those claims if they
5 do not have valid assignments.

6 The fact that we did not prevail at a
7 motion-to-dismiss stage or at the class-certification stage
8 does not relieve plaintiffs of their burden of proof at the
9 trial stage, Your Honor.

10 MR. STANOCH: And I don't think there's an
11 affirmative defense, Your Honor, to challenging the validity of
12 the assignments, especially not from the Teva defendant.

13 MR. OSTFELD: It's not part of our -- it's not an
14 affirmative defense, Your Honor. It's part of their case.
15 They have to demonstrate --

16 CHIEF JUDGE BUMB: Which you may have waived because
17 it was a dispositive motion that you didn't file.

18 Do you have the assignments, the unredacted
19 assignments you can turn over?

20 MR. STANOCH: I'd have to check with MSP's counsel.
21 I don't have them here, Your Honor.

22 CHIEF JUDGE BUMB: I mean, it's -- it's kind of
23 mind-boggling to me that we're arguing over something so
24 elementary.

25 MR. STANOCH: No, I agree, Your Honor. And that's

1 why we raised it now in the motion-in-limine context, that here
2 we are six years into this case, and now all of a sudden we're
3 going to be told that we have to have a multi-day testimony on
4 the assignments, which they have, and they've taken multiple
5 30(b)(6) testimony, and, as Mr. Ostfeld said, challenged
6 multiple times and have not prevailed.

7 MR. OSTFELD: Your Honor --

8 CHIEF JUDGE BUMB: Yes.

9 MR. OSTFELD: -- on May 12, 2021, I requested
10 unredacted copies of the assignments. On June 4, 2021,
11 plaintiffs declined to provide them. It is not my obligation
12 to chase them for something that is part of their obligation of
13 the burden of proof. It is also not waived if I do not raise
14 it on a summary judgment motion, Your Honor. This is not an
15 affirmative defense. This is not a waivable matter. This is
16 part of their elements of the case, their proof of the case.

17 CHIEF JUDGE BUMB: Can I just ask a very
18 straightforward question?

19 MR. OSTFELD: Yes, absolutely.

20 CHIEF JUDGE BUMB: On something that's just so simple
21 that might just totally, you know, throw a hand grenade into
22 the case, why would the defendant wait to this time to decide
23 --

24 MR. OSTFELD: We haven't, Your Honor. We've been
25 raising this over and over again. MSP has had endemic problems

1 sustaining their claims on the basis of inadequate assignments.
2 So it's not just one case five years ago. We provide a string
3 citation in our trial brief to numerous cases where this has
4 been dismissed. I don't think this is a defendant issue. I
5 think this is a plaintiff issue. They've been hiding the ball
6 on the assignments. They won't tell us what they paid, and
7 it's the most elementary thing they could do. Just give us the
8 unredacted assignments. Maybe we don't have an issue. Maybe
9 there is adequate consideration. But I can't understand why
10 for more than three years they've declined to provide the most
11 basic documents.

12 CHIEF JUDGE BUMB: Did you file a motion to compel?
13 Did you ever bring this up with Judge Vanaskie?

14 MR. OSTFELD: We're not required to, Your Honor.
15 It's not part of our proof. It's part of their proof. I would
16 have thought they would be happy to give us their assignments.

17 MR. STANOCH: Your Honor, he said he asked for it
18 three years ago, and we're sitting here today, he never moved
19 to reconsider. He never filed a letter brief with Judge
20 Kugler, with Special Master Judge Vanaskie. They served
21 supplemental discovery multiple times after the close of fact
22 discovery on MSP, and we gave them all that supplemental
23 discovery about all kinds of things, data, documents, et
24 cetera.

25 CHIEF JUDGE BUMB: Okay. Here's what I'm going to

1 say: I don't know why this is an issue this late in the game.

2 I think the fact that there was never a motion, I
3 think plaintiffs probably presumed there was no issue. I first
4 saw it I guess when I read the trial briefs. It raised a red
5 flag in my mind, like why is this issue being raised at this
6 late juncture. It seemed to be fairly elementary.

7 So I would hazard a guess that the plaintiffs believe
8 that it was not an issue and the defendants believed that it
9 was an issue. And the defendants never moved to compel. I get
10 it. I've been lectured you don't have to move to compel. I
11 get it. I've been lectured you don't have to move for summary
12 judgment. I get it.

13 But it seems to me that on something -- on an issue
14 like this, it should have been fleshed out a long time ago.
15 I'll refer to Judge Vanaskie. He'll work on resolving the
16 issue.

17 MR. OSTFELD: Thank you, Your Honor.

18 CHIEF JUDGE BUMB: Okay. What's the next motion?

19 MR. STANOCH: Was that on part of 34?

20 Thirty-five is simply that defendants won't suggest
21 that the TPPs and class members will retain the benefit and not
22 pass it along. It's just not casting aspersions, Judge, that
23 these insurance companies are going to take this money and line
24 their own pockets.

25 CHIEF JUDGE BUMB: They are not going to make that

1 argument, are you?

2 MS. BRANCATO: We are not, Your Honor.

3 MR. STANOCH: Thank you, Judge.

4 CHIEF JUDGE BUMB: I knew it.

5 Okay. Next.

6 MR. STANOCH: Number 36, frankly, Your Honor, if
7 you're going to hold *Daubert* hearings, this relates to Medicare
8 Part D offsets.

9 CHIEF JUDGE BUMB: Okay. We'll talk about that then,
10 okay.

11 MR. STANOCH: Yeah.

12 CHIEF JUDGE BUMB: 37. Okay. Same.

13 MR. OSTFELD: We think it's the same, Your Honor.

14 CHIEF JUDGE BUMB: Same.

15 38.

16 MR. STANOCH: It was my motion. I was going to say
17 that, but thank you, Mr. Ostfeld.

18 CHIEF JUDGE BUMB: Thirty-eight, same.

19 Thirty-nine, there will be no disparaging of the
20 insurance industry, not in my courtroom, not in any.

21 Okay. 40.

22 MR. STANOCH: Again, this is just a general one,
23 again, Your Honor, about not casting aspersions or --

24 CHIEF JUDGE BUMB: Okay. They're not going to do
25 that.

1 MS. BRANCATO: No, we're not.

2 CHIEF JUDGE BUMB: Right.

3 MS. BRANCATO: But on 40, in terms of relative
4 wealth, if punitive damages discovery or evidence is coming in,
5 then I think we should be able to present counter-evidence.

6 CHIEF JUDGE BUMB: Yes, I think that's right.

7 MS. BRANCATO: Thank you.

8 MR. STANOCH: Forty-one, defendants cannot argue that
9 TPPs are quote-unquote sophisticated users. It's an
10 affirmative defense. We don't think there's been a proffer of
11 any evidence. And, frankly --

12 CHIEF JUDGE BUMB: I don't think it's even applicable
13 here.

14 MR. STANOCH: Exactly.

15 MS. BRANCATO: We're not going to get into that.

16 CHIEF JUDGE BUMB: Yeah. Forty-two.

17 Well, if they say "we, us, our," they're not going to
18 tell us who they are, so dismissed as moot.

19 Okay. Forty-three. Cannot criticize plaintiffs'
20 attorneys.

21 For those of you who don't know me very well, one
22 thing that does not sit well with me is if there is great
23 acrimony between counsel. I expect civility amongst lawyers.

24 If this case -- and as I've said, I've read some
25 submissions, some pleadings where I was quite surprised, I will

1 not hesitate to require that attorney to attend CLE credits --
2 to get CLE courses for civics; I won't.

3 MR. STANOCH: Understood.

4 CHIEF JUDGE BUMB: Civility is so important to me.
5 Okay.

6 It's a great profession that we have, and we will
7 uphold it.

8 Forty-four.

9 MR. STANOCH: I think this is a similar one, Your
10 Honor, in terms of casting aspersions on the plaintiffs prying
11 into attorney-client information.

12 CHIEF JUDGE BUMB: Okay. Works both ways. You will
13 all get along so famously.

14 Forty-five.

15 MS. BRANCATO: Your Honor.

16 CHIEF JUDGE BUMB: Yeah.

17 MS. BRANCATO: Go ahead, Dave.

18 MR. STANOCH: Well, I was just going to say that this
19 one was not to make arguments that --

20 CHIEF JUDGE BUMB: A prime example of civility.
21 Thank you.

22 MR. STANOCH: Thank you, counsel.

23 Arguing about consumer damages or suggest that
24 consumers got a benefit. And, yes, we know the argument about
25 efficacy and economic worthlessness. That's one thing. But

1 not to overly beat the drum that, oh, and these people all had
2 their blood pressure controlled, it was really good, these --
3 these health plans want to keep a drug that worked for all
4 these people off the market and --

5 CHIEF JUDGE BUMB: They're not going to do that.

6 MR. STANOCH: Okay.

7 CHIEF JUDGE BUMB: Forty-six. They're not going to
8 do that either.

9 MR. STANOCH: Okay.

10 CHIEF JUDGE BUMB: Okay. Let's turn to the
11 defendants.

12 MR. STANOCH: Thank you, Judge.

13 MR. KASPARIE: Your Honor, I think I'm up on deck
14 again.

15 CHIEF JUDGE BUMB: Okay.

16 MR. KASPARIE: This one is just --

17 CHIEF JUDGE BUMB: What's the number?

18 MR. KASPARIE: Sorry. Yeah. It's 2649.

19 This is just specifically about the phrase or the
20 idea of sending a message to the defendants with their damages
21 award.

22 Obviously, punitive damages are at issue in this
23 case, and obviously that deterrence is a part of that, but we
24 think the idea of sending a message is inflammatory, and
25 telling the jury to send a message to the defendants is likely

1 to incite passion.

2 CHIEF JUDGE BUMB: Are you talking about at the
3 punitive damages stage?

4 MR. KASPARIE: Well, I think at any stage in the
5 trial we don't want --

6 CHIEF JUDGE BUMB: It would only be relevant in the
7 punitive damages.

8 MR. KASPARIE: I don't believe that they're
9 bifurcated, Your Honor.

10 CHIEF JUDGE BUMB: No, I know. But --

11 MR. KASPARIE: So I think one of our concerns might
12 be in opening argument, counsel for plaintiffs asking the jury
13 to send a message: At the end of this case, you're going to be
14 asked to send a message to defendants that X, Y or Z is
15 unacceptable. And we don't want that because we think that
16 that invites -- it inflames the jury's passions and could be --
17 well, it's certainly more prejudicial. We're worried about the
18 prejudice.

19 CHIEF JUDGE BUMB: So it's not bifurcated, but it
20 will be very clear what portion of the trial is related to that
21 stage, right?

22 Mr. Slater, how do you intend to present this?

23 MR. SLATER: When we learned that the defendants want
24 to try all issues at the same time --

25 CHIEF JUDGE BUMB: Yeah.

1 MR. SLATER: -- we're going to try all the issues. I
2 don't know that we intend to use the phrase "send a message."
3 If Your Honor says don't say "send a message," we wouldn't say
4 it. But punishment and deterrence are the two pillars of
5 punitive damages. And the deterrence part is you are sending a
6 message, you are telling the defendant this is what -- this is
7 our message to you. I mean, that's what the purpose of
8 punitives are. In a punitive case, you are allowed to make
9 statements you otherwise couldn't make.

10 So based on the case law, we looked, I don't think we
11 really should be limited from what we can say in terms of what
12 the jury's function is and what they can do through punitive
13 damages right from the outset.

14 CHIEF JUDGE BUMB: Well, all I'm asking is that when
15 you get up and you make your statements and then when you
16 present your case, that it be very clear that it's what portion
17 of the case you are presenting to the jury. And I think it
18 would be helpful, too, either I would do it or you could ask
19 for permission to do it, and say now this is this stage we're
20 asking for... Because what I definitely don't want to hear
21 throughout the entire trial that's not all related to the
22 punitive stage is "send a message, send a message, they're
23 terrible people." I don't want that.

24 MR. SLATER: Right. That will not happen. There's
25 no point to that. I mean, in opening we'll talk about it

1 because we'll explain the purpose of punitive damages.

2 CHIEF JUDGE BUMB: Okay.

3 MR. SLATER: In closing. But it's not going to be
4 something you're going to hear with every witness. I don't see
5 a point to that.

6 CHIEF JUDGE BUMB: Okay. Can you live with that?

7 MR. KASPARIE: I believe so, Your Honor.

8 CHIEF JUDGE BUMB: Yeah. I mean, that's what
9 punitives are intended to do, so, yeah. Okay.

10 MR. KASPARIE: I think I also have the privilege of
11 doing the second one as well. This is just, we don't want to
12 inject, similar to ZHP's motion regarding Remonda Gergis, there
13 are several other documents that we believe that the plaintiffs
14 are likely to move to admit that revolve around regulatory
15 issues that are not related to valsartan.

16 I think that there might be a slight dispute between
17 us and plaintiffs about whether or not they relate to the
18 specific facilities at issue, but we think that those are --
19 they're just not germane to the issues.

20 CHIEF JUDGE BUMB: They have to relate to valsartan.
21 It's sort of the -- kind of where we started with, the -- what
22 was it called? The Meridan report.

23 MR. KASPARIE: Yeah.

24 CHIEF JUDGE BUMB: And the other report that began
25 with a T.

1 Yeah. It would have to relate to valsartan or there
2 has to be a connecting of the dots somehow. It can't just be
3 across the board. Okay?

4 MR. STANOCH: Your Honor, just for plaintiffs really
5 quickly on that.

6 CHIEF JUDGE BUMB: Yeah.

7 MR. STANOCH: We'll certainly want to connect the
8 dots. We just want to be clear that a number of the
9 evidentiary documents and testimony will show, will talk about
10 what we argue is a lack of appropriate cGMP oversight, for
11 example, of their suppliers. So, for example, Teva and
12 Torrent, that they had lax oversight of their supplier, ZHP.

13 That does not necessarily mean, oh, this email says
14 oh, valsartan API, there's an issue. But it may have other
15 issues about the same facility at which the valsartan API
16 was --

17 CHIEF JUDGE BUMB: There has to be a connection,
18 okay?

19 MR. STANOCH: Absolutely.

20 CHIEF JUDGE BUMB: If it's the same facility, it
21 still has to be a connection to valsartan more directly. It
22 can't be an entire sort of a character assassination. It's
23 sort of the flip side -- or not the flip side, I guess it's the
24 same side as the Meridan report.

25 The reason I didn't let the Meridan report in is

1 because some were compliant, some drugs were compliant, some
2 weren't. And I don't want this to come into where the jury is
3 just trying to sift together, well, what was it with valsartan
4 and what was it with other products. I don't want that to be
5 happening. And to just say, well, they were just so, you know,
6 lax and they didn't care across the board, I think, is a 401,
7 403 issue.

8 MR. STANOCH: And it may be touch and go on certain
9 issues, because, again, if there is an issue systemically about
10 properly monitoring chromatography testing, right, that's
11 something that ties to the valsartan API, but the word
12 "valsartan" won't be in that document, Judge, but that's
13 certainly highly pertinent.

14 CHIEF JUDGE BUMB: Well, the point is, is if it's
15 systematic -- what did you say? Systematically?

16 MR. STANOCH: Systemic or systematic.

17 CHIEF JUDGE BUMB: Systemically, okay, that's one
18 argument that has more probative value.

19 If it's, well, in some they were, in some they
20 weren't, in some they were, then it has less probative value.

21 So if you're going to introduce the evidence and you
22 have a question for me about, well, is it permissible or not,
23 then you better front it. Understood?

24 MR. STANOCH: Understood, Your Honor.

25 CHIEF JUDGE BUMB: Okay. Because I will be, again,

1 as the gatekeeper, trying to connect the dots under Rule 401 to
2 make sure that it's more likely to lead to relevant evidence or
3 is this what I will just characterize as "character
4 assassination."

5 MR. STANOCH: Understood. And obviously to the
6 extent the door is open, we may offer that as well. If they
7 say --

8 CHIEF JUDGE BUMB: Well, that's a different issue.

9 MR. STANOCH: -- we're good companies that followed
10 the regs.

11 CHIEF JUDGE BUMB: Okay. That's a different issue.

12 MR. STANOCH: Thank you, Judge.

13 CHIEF JUDGE BUMB: That's it? Yeah?

14 MR. KASPARIE: That's it for me.

15 CHIEF JUDGE BUMB: Okay. Are we to the "reptile
16 theory" yet? No.

17 MS. ROSE: No. We're on discovery disputes.

18 CHIEF JUDGE BUMB: Okay.

19 MS. ROSE: Which is 3 of that same document.

20 CHIEF JUDGE BUMB: That doesn't come in at all. You
21 mean the jury will hear that there were discovery disputes?

22 MS. ROSE: Yeah. It's our understanding the
23 plaintiffs don't oppose this motion.

24 CHIEF JUDGE BUMB: Okay.

25 MS. ROSE: And the only discovery disputes that they

1 want to bring in relate to the sanctions motions. So I think
2 probably best resolved with respect to the conduct at issue in
3 the sanctions motion.

4 CHIEF JUDGE BUMB: Well, that will come in with
5 some -- well, we're not done with that yet because Judge
6 Vanaskie just ruled yesterday, and you folks will address it.
7 But -- okay. So it's moot except for that issue, and I'll talk
8 about it, okay.

9 MR. SLATER: Your Honor, just to be clear and make
10 sure that we're both on the same page, as we said in our brief,
11 we're not looking to litigate discovery issues with the jury,
12 but to the extent, for example, a witness, their custodial file
13 had no documents and there was missing documents for five
14 years, or --

15 CHIEF JUDGE BUMB: That's not a discovery dispute.
16 That's evidence.

17 MR. SLATER: Understood.

18 CHIEF JUDGE BUMB: Okay.

19 MR. SLATER: We see the same distinction.

20 CHIEF JUDGE BUMB: All right. Unnecessary references
21 to cancer-related terms.

22 MS. BRANCATO: Yes, Your Honor. This may be largely
23 moot from your ruling earlier --

24 CHIEF JUDGE BUMB: Yeah.

25 MS. BRANCATO: -- that we're going to refer to

1 carcinogens and whether they rendered things worthless or not.
2 We just wanted to mention it because it has been an issue, and
3 it's an issue in some currently designated deposition
4 testimony.

5 So inflammatory comments, and this goes in line with
6 the reptilian theory brief, I know is next, about would your
7 family members have taken this drug if they knew they were
8 going to get cancer? Would you have told them to take this,
9 that kind of thing. We don't think it's appropriate.

10 CHIEF JUDGE BUMB: No. They're not going to make
11 those arguments.

12 MS. BRANCATO: Thank you, Your Honor.

13 CHIEF JUDGE BUMB: It's too inflammatory.

14 Five.

15 MS. BRANCATO: I think this is along the same lines
16 we just talked about, Your Honor.

17 CHIEF JUDGE BUMB: Okay.

18 Six.

19 MR. SLATER: Just -- we just went over it. I just
20 want to make sure I understand.

21 I don't think we were looking to make the argument
22 that was just framed. But in terms of the reptile theory
23 motion, when counsel said "same," I don't think it's the same
24 issue. We're certainly allowed to talk about the rules that
25 the defendants were supposed to follow; that they were

1 regulated; that there were all sorts of standards they were
2 supposed to follow. I mean, the --

3 CHIEF JUDGE BUMB: Yeah.

4 MR. SLATER: And there's plenty of law here that says
5 we're absolutely allowed to get into these issues and talk
6 about safety rules and practices. That's -- if we're going to
7 talk -- if cGMP is going to be tried, that's safety right
8 there. And those are -- those rules are meant to protect the
9 safety of the drugs and the patients taking them.

10 MS. BRANCATO: I think, Your Honor, if I may just
11 quickly, we don't obviously have a problem with talking about
12 cGMPs and safety and efficacy. Where we get a concern is
13 things like in the first page of their MSJ brief where they say
14 things like "clear and present danger to the U.S. drug supply."
15 And what we're talking about is valsartan and this very
16 specific circumstance here, and that's what we would have an
17 objection about.

18 MR. SLATER: I'm not sure about -- that might be
19 something that was said in the brief. But if the defense is
20 going to talk about lifesaving drugs and how safe it is, we're
21 certainly allowed to talk about the significance in terms of
22 worthlessness or value of the contamination.

23 CHIEF JUDGE BUMB: It's just a balancing act. You'll
24 be guided accordingly. You're not going to get up and say, oh,
25 they're just terrible companies, they just want to kill

1 everybody. We know you're not going to do that.

2 MR. SLATER: That will not be said, absolutely not.

3 CHIEF JUDGE BUMB: Okay. That's the point. They're
4 just trying to keep you in check, that's it.

5 MS. BRANCATO: Thank you, Your Honor.

6 CHIEF JUDGE BUMB: Okay. Six.

7 MS. BRANCATO: Your Honor, on six, this is similar to
8 some of the discussions we've had earlier today about
9 misleading the FDA versus misleading the plaintiffs in this
10 particular case, and that's really what our concern is.

11 CHIEF JUDGE BUMB: Yeah.

12 MS. BRANCATO: If plaintiffs are, as we see in their
13 opposition, pointing to false representations made to the FDA
14 by ZHP and Teva, for example, that's where we have an issue.
15 The representations need to be made to the TPPs and what was
16 false and misleading about those particular representations.
17 And putting -- mentioning the FDA so many times I think runs
18 into potential *Buckman* issues, but also is confusing and
19 misleading to the jury.

20 MR. SLATER: I'm confused by the motion to some
21 extent. First of all, starting with *Buckman*, there's obviously
22 no *Buckman* issue here because that would have to be our only
23 claim in the case, which it is not. But it is factual that,
24 for example, in the DMF amendments, for example, filed by ZHP,
25 they said there were no genotoxic impurities in the drugs. And

1 if the defense is going to try to talk about what the FDA did
2 or didn't catch, we're going to be able to show that they did
3 mislead the FDA and misrepresented things and didn't provide
4 full information.

5 CHIEF JUDGE BUMB: So it can come into evidence that
6 the defendants -- the statements that the defendants made to
7 the FDA, that's admissible.

8 MS. BRANCATO: I think that's fine, Your Honor. As
9 long as it doesn't go so far as arguing that because defendants
10 made these statements it was a misrepresentation to the FDA,
11 which therefore is some misrepresentation to the TPPs.
12 Conflating the FDA and the TPPs I think is where our concern
13 arises.

14 CHIEF JUDGE BUMB: Okay.

15 MR. SLATER: I'm not sure how we would do that.

16 CHIEF JUDGE BUMB: Okay. Good. Then don't. Okay.

17 (Laughter.)

18 CHIEF JUDGE BUMB: Seven, evidence or argument
19 concerning corporate intent, motive, and ethics.

20 MR. OSTFELD: Yes, Your Honor. And to be clear, this
21 is narrowly focused on the exclusion of expert evidence or
22 testimony pertaining to defendants' overall corporate intent,
23 motive, or ethics. There have been no experts proffered in
24 this case with having the qualifications or a reliable basis to
25 testify about any of the defendants' intent, motive, or ethics.

1 This doesn't prevent --

2 CHIEF JUDGE BUMB: Yeah. I think the only evidence
3 is that, and I saw some evidence, is that, you know, of
4 financial profits, right?

5 MR. SLATER: Yeah. I mean, there was certainly
6 motives to make money and there's -- we gave you some of the
7 quotes.

8 To me this is the flip side to we're really good
9 companies, we shouldn't be saying, and we're not looking to
10 say, you know, in general these were terrible companies. We're
11 looking to focus on the conduct relevant to this case. That's
12 why we thought the flip side is if they don't want us to talk
13 negatively in general, they shouldn't talk positively in
14 general. We should focus on the facts and what they say to the
15 jury about the claims.

16 CHIEF JUDGE BUMB: Right.

17 MR. OSTFELD: Your Honor, this motion isn't directed
18 to factual testimony. They can question our corporate
19 witnesses about this. They just can't have their experts opine
20 on our corporate motives, ethics or intent. The experts don't
21 have a basis to do that.

22 CHIEF JUDGE BUMB: I agree. Okay.

23 Eight, evidence of statements or actions by
24 regulatory agencies outside the United States.

25 MS. LOCKARD: Your Honor, this is my motion as well.

1 So our concern here is that the plaintiffs will seek
2 to expand this litigation to talk about OUS, foreign regulatory
3 activities, standards, statements, that don't apply in the
4 context of this case with the drugs sold in the U.S.

5 There has been a macro discovery order that excluded
6 correspondence with the foreign regulatory authorities. That's
7 not even a part of discovery. I understand plaintiffs'
8 position is that if the defendants have relied on a
9 regulatory -- a foreign regulatory standard or guidance, that
10 that is fair game. And I think that's fair. If there is
11 something and they can establish that one of the defendants
12 relied on something from the EMA in formulating its response to
13 the nitrosamine issue in the U.S., then that's fair game. But
14 just to bring in here's what's happening around the world or
15 with Teva's facilities in other countries not involving
16 nitrosamine being sold in the U.S., I think that should be
17 excluded.

18 CHIEF JUDGE BUMB: And you agree?

19 MR. SLATER: I can't agree with that, because I think
20 that's much broader than what I would agree with. I think we
21 have to talk about what's factual.

22 First of all, Judge Schneider permitted foreign
23 regulatory discovery, extensive foreign regulatory discovery,
24 and we cited his ruling on page 19 of our opposition brief in
25 Footnote 6.

1 So that is in the case. ZHP, for example, actually
2 cited the EMA guidelines in their DMFs for both manufacturing
3 practices as one of their sources of information. They had
4 back-and-forths at the same time --

5 CHIEF JUDGE BUMB: If they rely on it, then you
6 can -- then it opens the door for you.

7 MR. SLATER: I would think. And there's also
8 statements and information from the European, for example,
9 regulatory agency that talked about the dangers of these drugs.
10 That's all admissible for notice. All the witnesses admitted
11 they were following all of these guidelines. They all applied
12 to the same drugs, because the manufacturing facility was
13 manufacturing for the U.S. and other places. So they --

14 CHIEF JUDGE BUMB: If the witnesses say that they
15 relied on them, then it's relevant.

16 MR. SLATER: Okay.

17 MS. LOCKARD: I think that's different from providing
18 for notice purposes. To say that one country issued this
19 statement, therefore, these companies were on notice, I think
20 that's outside of what we are agreeing to.

21 CHIEF JUDGE BUMB: What I said is if the witnesses
22 say that they relied on them, then it's relevant, right?

23 MR. SLATER: If they --

24 CHIEF JUDGE BUMB: They have to know about them.

25 MR. SLATER: Oh, right. That's right. There's

1 nothing that we're going to talk about that the witnesses for
2 the companies didn't know about.

3 CHIEF JUDGE BUMB: Okay.

4 Okay. Nine, I think we talked about.

5 MS. BRANCATO: Yes, Your Honor. I think we're going
6 on nine. The only note I would make is that plaintiffs'
7 opposition mentions two documents. I think we should work that
8 out separately and come back to you if they have any issues on
9 those specific --

10 CHIEF JUDGE BUMB: I think you should work it out.

11 MS. BRANCATO: Thank you, Your Honor.

12 MR. SLATER: You mean the redactions?

13 MS. BRANCATO: Yes.

14 MR. SLATER: Okay.

15 CHIEF JUDGE BUMB: Good. Work it out, please.

16 Ten, we talked about ten.

17 MS. BRANCATO: Ten is also not an issue.

18 MR. SLATER: Right. We agree with the individuals...

19 CHIEF JUDGE BUMB: Eleven.

20 MS. LOCKARD: Eleven, Your Honor, I think this, in
21 part, was resolved in connection with the motion that
22 Mr. Harkins argued this morning with relation to Teva's foreign
23 API's supplier, TAPI. So I think that piece of it has been
24 ruled upon.

25 The one part that hasn't been addressed today is, as

1 you may know from reading the papers, you know, obviously we're
2 here about the ZHP API. There was an entire other distribution
3 stream involving API from Mylan, which is not at issue in this
4 TPP case, right? For a later time, for a later litigation
5 proceeding.

6 What plaintiffs want to do, though, is they want to
7 bring into the TPP case the ZHP case, the factual timeline for
8 when Teva found out about the Mylan API, what they did about
9 it, what Mylan was telling Teva about the nitrosamines in
10 Mylan's API, and all of that after the recall of the ZHP API
11 product. So all after the fact. So all of this should be
12 irrelevant and excluded. Otherwise, we have to get into the
13 side trial what's happening with Mylan.

14 CHIEF JUDGE BUMB: So it's irrelevant, right?

15 MR. STANOCH: Your Honor, we haven't even -- Judge
16 Kugler already denied their *Daubert* motion as to our cGMP
17 expert in talking about Teva's cGMP compliance around the
18 recalls. It's a timeline in that summer. He looks at that
19 about what Teva's doing, and it includes the API from ZHP and
20 Mylan and two or three other nondefendants. And he opines on
21 that about looking at all of that in reaction to the initial
22 news about the contamination from ZHP. And he opines -- and
23 Judge Kugler is allowing him to opine at trial -- about what
24 Teva did or did not do at that time in that process.

25 CHIEF JUDGE BUMB: Okay.

1 MR. STANOCH: Because what they did -- what Teva did
2 was it released its -- you heard about the hold this morning --
3 they released the hold on the other products without even
4 testing them. And our expert essentially says you heard there
5 was an issue with ZHP's. You should have probably tested all
6 of them before you released it. That's it. We're not getting
7 into -- there's a whole other ream of paper about Mylan API and
8 the story then goes on for months. We're not trying to prove
9 Mylan API contamination now. We're not trying to prove Teva
10 did not oversee Mylan as an API supplier properly. We're just
11 saying, in reaction to the news from ZHP about the NDMA, that
12 Teva did not follow its own SOPs and cGMP to properly assess
13 the risk associated that was being disclosed. It's a very
14 narrow time frame, Judge.

15 CHIEF JUDGE BUMB: Okay.

16 MS. LOCKARD: The *Daubert* ruling related to the
17 methodology of plaintiffs' expert and whether that expert was
18 qualified and presented reliable methodology to offer these
19 opinions.

20 It did not address the issue of whether, under
21 evidentiary standards, the underlying facts regarding the Mylan
22 timeline are even relevant to this TPP case. That was reserved
23 for the motion-in-limine stage.

24 The fact that they can, you know, satisfy the hurdle
25 of methodology for their expert to talk about this fact is an

1 entirely different inquiry.

2 CHIEF JUDGE BUMB: Yeah. I don't think the Mylan
3 timeline comes in.

4 MR. STANOCH: It's part and parcel of the exact same
5 thing that's happening in realtime contemporaneously, Judge. A
6 matter of just a few weeks between June and July.

7 CHIEF JUDGE BUMB: Right.

8 MR. STANOCH: Our expert and our evidence is not
9 going to go beyond that. It's just saying once they got the
10 news, Teva's own documents are talking about all of this at
11 once, right? And they don't test all the other products,
12 Mylan, other defendants, they don't test it at all, and they
13 just look at -- start looking at ZHP. That's all we're talking
14 about, because --

15 CHIEF JUDGE BUMB: For that limited fact?

16 MR. STANOCH: Yes.

17 CHIEF JUDGE BUMB: That's all you want to get it in;
18 that they didn't look at anybody else's other than ZHP's?

19 MR. STANOCH: Yes. And that they should have. And
20 it goes to sort of the egregiousness of their conduct and their
21 state of mind that they still want -- they had knowledge.

22 CHIEF JUDGE BUMB: You can introduce that limited
23 fact.

24 MR. STANOCH: All right.

25 CHIEF JUDGE BUMB: It just seems to be so not that

1 probative, but --

2 MS. LOCKARD: But, I mean, the point they want to
3 make is that once we learned about ZHP, that we should have
4 then started asking our other suppliers.

5 CHIEF JUDGE BUMB: I understand.

6 MS. LOCKARD: And then they want to say, well, there
7 was a back-and-forth between Mylan, about getting information
8 from Mylan. This is in the sequencing months following the
9 recall for ZHP.

10 CHIEF JUDGE BUMB: Let me -- let me reserve on that
11 motion, because I will be better informed when I see the
12 evidence coming in.

13 MR. STANOCH: Yes, Your Honor.

14 CHIEF JUDGE BUMB: And that may be taking us down to
15 a path I don't want us to be taken down.

16 MR. STANOCH: We would not go that far.

17 CHIEF JUDGE BUMB: So I'm going to reserve on that
18 aspect.

19 MR. STANOCH: Thank you, Judge.

20 MR. SLATER: And I just want to confirm, I think we
21 are on the same page, we confirm this motion is not intended to
22 preclude the Novartis evidence with ZHP, correct?

23 We briefed it that we assumed that that's not
24 encompassed. I just want to make sure, which I think Your
25 Honor is familiar with, the fact that Novartis in Europe

1 purchased -- was provided the API and they actually discovered
2 the NDMA and forced ZHP to disclose it.

3 I'm assuming that we're not trying to preclude that
4 evidence.

5 MS. ROSE: I just want to be clear, Mr. Slater, so
6 you're referring to just the fact that Novartis was the entity
7 that ZHP communicated with in determining that?

8 MR. SLATER: What I'm referring to is what we said in
9 our brief, that this motion was focused on sales of -- let me
10 just get to the title of it -- sales to foreign entities sold
11 outside the U.S.

12 The API provided to Novartis and Novartis' reaction
13 to that is a central fact in this trial. I was just confirming
14 that this motion is not intended to cover that issue.

15 MS. ROSE: That was not the intent of this motion.

16 MR. SLATER: Okay. Just making sure that's not --

17 CHIEF JUDGE BUMB: Okay. So that takes care of --

18 MS. ROSE: Your Honor, I'm so sorry, and I hate to do
19 this. I hate to go back, but just something was raised on
20 Motion in Limine 3 at the very end by Mr. Slater that I wanted
21 to respond to, and everything happened very fast.

22 CHIEF JUDGE BUMB: Go ahead.

23 MS. ROSE: At the very end, Motion in Limine 3 was
24 about discovery disputes. And everyone sort of agreed
25 discovery disputes are not coming in. At the very end

1 Mr. Slater said but we can talk about the fact that a witness
2 doesn't have documents in their custodial file or doesn't have
3 a lot of documents. I'm very concerned about that because that
4 gets into the issue of suggesting there was some spoliation.

5 CHIEF JUDGE BUMB: No. I'll monitor it. And
6 certainly if it wasn't in the file, it might -- that tends to
7 have probative -- if it wasn't in the -- and I know we're
8 discussing it, it's the email that's at issue really. But it
9 has probative value. But then to go beyond that to say, well,
10 we had to go before Judge Vanaskie or we -- none of that is
11 coming in. I mean, it's just -- it is probative that it was in
12 one file and not the other. That's probative.

13 MS. ROSE: I just want to be clear.

14 CHIEF JUDGE BUMB: It's not going to lead to any
15 inference of spoliation. If it does, I'll instruct the jury.

16 MS. ROSE: Thank you, Your Honor.

17 CHIEF JUDGE BUMB: Okay.

18 MR. SLATER: Yeah. The general point, we briefed it
19 that we were just going to do it in accordance with the cases
20 that we cited, that it's a fact that certain documents were
21 available, certain documents were not available. Not --
22 putting aside the issues that have been dealt with in Judge
23 Vanaskie's order that Your Honor is going to address, that's
24 obviously a different issue.

25 CHIEF JUDGE BUMB: Okay. That takes care of 2649,

1 right?

2 MS. ROSE: Yes, Your Honor.

3 CHIEF JUDGE BUMB: Okay. Are there any -- let me
4 turn to the trial briefs. Do we really have to deal with any
5 of this? It just seems so...

6 MR. OSTFELD: Well, Your Honor, one issue. It's
7 plaintiffs' issue, so I'll let them speak to this.

8 CHIEF JUDGE BUMB: Yeah.

9 MR. OSTFELD: But then we had a question of punitive
10 damages discovery that may be best addressed today.

11 CHIEF JUDGE BUMB: Well, it should be updated
12 financial information.

13 MR. OSTFELD: Your Honor, I don't know if -- I don't
14 want to step on plaintiffs' presentation of the issue.

15 MR. SLATER: I could make it really brief.

16 CHIEF JUDGE BUMB: Yeah.

17 MR. SLATER: All we're asking for at this point is
18 that before trial that we're provided updated financial
19 information regarding gross revenues and net worth of the
20 companies, because that's what we need in order to present our
21 punitive damages and we need it updated.

22 CHIEF JUDGE BUMB: So please provide it.

23 MR. OSTFELD: Your Honor, I certainly understand.
24 The only issue I would raise, this goes to the point Your Honor
25 made earlier when ruling and denying ZHP's motion to amend.

1 This information was never requested in discovery.

2 CHIEF JUDGE BUMB: Ever?

3 MR. OSTFELD: Ever.

4 MR. SLATER: I'm trying to think about whether or not
5 we actually requested it previously. I'll tell you what
6 happened. We assumed the case was going to be bifurcated.

7 CHIEF JUDGE BUMB: You're going to tell Judge
8 Vanaskie what happened. I'm going to refer to him.

9 MR. SLATER: We told him, and then he said come back
10 here, but I guess we'll go back around.

11 JUDGE VANASKIE: I'll take it under.

12 MR. SLATER: Fair enough, Judge.

13 CHIEF JUDGE BUMB: Take it under.

14 If it wasn't requested, here we are on the eve of
15 trial, and I don't know what to tell you. If there was a
16 misunderstanding because you thought it was going to be
17 bifurcated, okay, that's something that Judge Vanaskie is far
18 more familiar with than I was, so...

19 MR. SLATER: Thank you.

20 CHIEF JUDGE BUMB: We're not going to try, you know,
21 we're not going to try a case by trickery or deceit obviously.
22 If there was a misunderstanding and the issue of bifurcation,
23 nonbifurcation came up late in the game and that explains it,
24 so be it. But in any event, much of this is publicly available
25 in any event; is that right?

1 MR. SLATER: Correct. And it is. And we could use
2 the publicly available information, for the most part. But we
3 thought the better practice was to make sure that the
4 defendants confirmed to us this is the updated information so
5 we didn't come into court with the updated information from the
6 day before we opened and they say, well, that's not accurate,
7 there was a problem with it. We'd rather avoid disputes.

8 CHIEF JUDGE BUMB: Well, may I make a suggestion?
9 Confer with them. Because if you can introduce it publicly and
10 they would rather that you get it from them, then I would
11 suggest that that's the way to go.

12 MR. SLATER: Okay. We'll talk about that. Hopefully
13 we can work that out.

14 CHIEF JUDGE BUMB: Because there's been no final
15 pretrial order entered, right? It's been submitted but not
16 signed.

17 MR. SLATER: It's not been entered yet.

18 CHIEF JUDGE BUMB: That's what I'm saying. So the
19 exhibit list isn't finalized yet, so...

20 MR. SLATER: And I think we actually included this
21 information on our exhibit lists.

22 CHIEF JUDGE BUMB: Okay. So all I'm saying is, do we
23 really have to quarrel about this?

24 MR. SLATER: No, I don't.

25 CHIEF JUDGE BUMB: And maybe Judge Vanaskie doesn't

1 need to get involved, okay?

2 Any issues on the trial brief that have to be
3 resolved that are so --

4 MS. ALLON: Your Honor, there are a couple others.
5 I'm pretty confident we can meet and confer with the plaintiffs
6 and resolve them.

7 CHIEF JUDGE BUMB: Good. Thank you.

8 MS. ALLON: I think they fall in the category that
9 you might be scratching your head about why we couldn't do that
10 before today, but...

11 MR. SLATER: I'm pretty confident we really want to
12 work it out among ourselves.

13 MS. ALLON: Yeah.

14 CHIEF JUDGE BUMB: I would appreciate that. I mean,
15 some of these things you folks are quarreling about, it really
16 is head scratching, I will say.

17 Okay. All right. Okay. Trial date. Let's talk
18 about a trial date and then we'll talk about *Daubert* hearings.
19 We'll do the *Daubert* hearings when we can, but let's work
20 backwards from the trial date.

21 Have you folks conferred on the trial date? Oh, I
22 should have worked from your agenda issues. How did we do on
23 them?

24 I do know -- I don't want to be -- I do want you
25 folks to catch your flights. So how did I do on the agenda

1 letters?

2 MR. SLATER: My guess is you exceeded them.

3 MS. ALLON: Yeah. We did quite well.

4 CHIEF JUDGE BUMB: Oh, good. Okay, let's see.

5 MS. ALLON: Well, number one is the trial date, so...

6 CHIEF JUDGE BUMB: Okay. Let me just look. I'll
7 look at -- okay. I have Ms. Lockard's letter here. Let's see.
8 Trial date. Number one, yes.

9 Oh, the Mansouri study. Okay. In limines, we did
10 that. General causation.

11 Motion to amend.

12 Oh, yeah, we did pretty good. Okay.

13 Because what we can do then is we could pick up on
14 some of these little things that I didn't get to when we do the
15 *Dauberts*.

16 All right. Trial date. Have you folks talked about
17 trial dates?

18 MR. SLATER: We have not, Your Honor.

19 CHIEF JUDGE BUMB: Oh, you haven't.

20 MR. SLATER: We got your notice about November 2024.
21 I think from the plaintiffs' perspective, we assumed it would
22 be the start of November 2024. But we have not talked much
23 with the defense about it other than in the hallway a little
24 bit.

25 MS. DAVIDSON: Well, Your Honor, we did raise with

1 Adam yesterday that ZHP has a trial with Judge Shipp that
2 starts December 3rd, with a mandatory pretrial conference
3 November 26th.

4 MR. SLATER: I think you said ZHP has a trial.

5 MS. DAVIDSON: ZHP's counsel. I think that was
6 clear.

7 CHIEF JUDGE BUMB: Let me get my calendar.

8 MS. ALLON: So, Your Honor, I think --

9 MS. DAVIDSON: I'm not really done.

10 We have a trial with Judge Shipp in the J&J talc
11 litigation, Your Honor. So I just want to make sure that a
12 November trial would be feasible with the December 3rd trial
13 date and with two mandatory pretrial conferences in November.
14 I can hand up his scheduling order if that will be helpful for
15 you.

16 MR. SLATER: Is that the order from yesterday?

17 MS. DAVIDSON: Yes.

18 MR. SLATER: Okay.

19 CHIEF JUDGE BUMB: Judge Shipp's scheduling order?

20 MS. DAVIDSON: Judge Shipp's scheduling order.

21 CHIEF JUDGE BUMB: Oh, I should have gone earlier.

22 MS. ALLON: So, Your Honor, what I was going to say
23 is we had a conversation with Judge Kugler about how long this
24 trial would take.

25 CHIEF JUDGE BUMB: Yeah. How long?

1 MS. ALLON: So the defendants said four weeks, and
2 the plaintiffs said three to five weeks, depending on general
3 causation. And Judge Kugler set a four-week trial. And Judge
4 Kugler's practice was 9:00 to 2:00 four days a week. So he
5 essentially gave us 80 hours, if you calculate the hours. I
6 understand that Your Honor's practice is to hold trials five
7 days a week. And so --

8 CHIEF JUDGE BUMB: 9:00 to 2:00, five days.

9 MS. ALLON: Right. Same hours, five days a week.

10 So we did the math. What we figured out is if we
11 start the first Monday in November, there are three court
12 holidays in November.

13 CHIEF JUDGE BUMB: Uh-huh.

14 MS. ALLON: Veterans Day, Thanksgiving, the day after
15 Thanksgiving. But we can start the first Monday in November,
16 and it can go to the jury on November 26th, and that would give
17 us the same 80 hours that Judge Kugler was going to give us. I
18 actually have a vested interest in this because I'm having a
19 baby December 1st, so I'd really like to be done before then.
20 So we thought everybody can be happy, we'll get the same amount
21 of hours that we had all agreed to live with under Judge
22 Kugler's guidance and be finished in November.

23 CHIEF JUDGE BUMB: All right. Let me just check my
24 calendar. Thank you.

25 MR. SLATER: And, Your Honor, I'm not sure if -- I

1 think you were focused on the date we're going to start. We
2 can certainly talk more about how long the trial is going to
3 take. I think there's still things that need to be resolved
4 and done before we --

5 CHIEF JUDGE BUMB: It's going to take three and a
6 half weeks, no more.

7 MS. LOCKARD: Your Honor, when we were discussing
8 trial conflicts, I don't think this is going to be a conflict
9 if we're three and a half weeks, but I do have a case set in
10 the Western District of Washington before Judge Settle starting
11 December 3rd as well.

12 CHIEF JUDGE BUMB: That's why it's only going to take
13 three and a half weeks.

14 Look, I have to give you folks a trial date. We have
15 to start it. Because nobody's schedule is going to be
16 conflict-free.

17 And then always what inevitably happens is I adjourn
18 my trials and then the trials that were posing potential
19 conflicts, they go away. And it's -- and, you know, it's time
20 that we move this case.

21 I just want to make sure that I'm fairly available.

22 I have a few criminal matters. It's a good time for
23 me. I just have some criminal matters; we can take a few
24 breaks. But should we start it a little -- November 1st is on
25 a Friday.

1 MS. ALLON: Yeah. I feel like November 4th, Your
2 Honor. That's the first Monday in November. And that's what
3 my calculation when I said the 80 hours through the 26th was
4 based on starting Monday, November 4th, and adjourning on the
5 11th, which is a court holiday.

6 MR. SLATER: What about selecting the jury the week
7 before?

8 CHIEF JUDGE BUMB: Yeah. I was just going to ask
9 that.

10 MR. SLATER: And then we know we're going to open on
11 a certain day and time, and then we can have some certainty
12 with our experts, et cetera.

13 CHIEF JUDGE BUMB: Because it will take a while to
14 get the jury, it just will, with a case of this length.

15 MR. OSTFELD: Your Honor, the week before I do have a
16 two-day arbitration on the 28th and the 29th. If we could
17 select the jury at the end of that week, I would still be
18 available.

19 (Counsel conferring.)

20 THE COURT REPORTER: I'm sorry?

21 MS. ALLON: Yeah. I have a conflict on the 31st.
22 I'm not available on the 31st. I'm available earlier.

23 CHIEF JUDGE BUMB: Well, I would imagine we would
24 send out questionnaires. You folks would have to work on the
25 questionnaires. We would send out the questionnaires to the

1 jurors and then you'll exercise your for-causes on the
2 questionnaires, which I have not ever -- to be honest, I don't
3 know that I've ever done that. But I think in a case like
4 this, it would probably be more productive.

5 MS. LOCKARD: We have worked together on a
6 questionnaire, Your Honor.

7 CHIEF JUDGE BUMB: Did you?

8 MS. LOCKARD: I think we had a few disputes, just a
9 handful. And those were submitted to the Court.

10 We can -- well, how would you like us to present
11 those to you?

12 CHIEF JUDGE BUMB: Your disputes on the
13 questionnaires were submitted to me?

14 MS. LOCKARD: No; submitted to Judge Kugler
15 previously.

16 CHIEF JUDGE BUMB: Oh. Well, as I told you in the
17 beginning, I want everything on the docket, okay. Emailing it
18 and sending it, it's just -- so if you have a dispute and you
19 can't agree on the questionnaire, then just file it on the
20 docket and I'll give you my ruling.

21 And it would be helpful if it's a joint submission,
22 so a joint submission by the defendants and the plaintiffs,
23 okay?

24 MS. LOCKARD: Sure.

25 MR. SLATER: Yeah. I think we had it redlined that

1 way to show what the alternatives were.

2 CHIEF JUDGE BUMB: Oh, that would be helpful.

3 MS. LOCKARD: Yeah. Okay.

4 MR. SLATER: I mean, we're fine with even picking,
5 whatever works for Your Honor, picking the jury even earlier
6 than the week before if you want to do that.

7 CHIEF JUDGE BUMB: No. I'll do it the -- I mean, it
8 probably is going to take -- it's going to take a little while
9 to pick the jury.

10 Well, let's start picking the jury on October 30th,
11 and we'll go through that week, and then we'll start the trial
12 on the 4th, okay? So whatever it takes. And then I'll have --
13 let me just make sure.

14 Halloween, yeah. So we'll start picking the jury on
15 the 30th, and we'll make good use of that time that week. The
16 30th, 31st and November 1st. And if we get the jury, then
17 we'll spend a day, you know, if there's any issues.

18 MS. DAVIDSON: Thank you, Your Honor.

19 MS. ALLON: Yeah. That's fine, Your Honor. I have a
20 conflict on the 31st, but I'll have somebody cover for me. As
21 long as we can agree that we won't open before the 4th.

22 CHIEF JUDGE BUMB: Right.

23 MS. ALLON: Okay. Then that's fine.

24 CHIEF JUDGE BUMB: Okay.

25 Yeah? Good?

1 Let's look at the *Dauberts*. So I want to do the
2 *Daubert* hearings. I guess you're probably going to need to
3 reach out to your experts, huh?

4 MS. ALLON: Yes. I think --

5 CHIEF JUDGE BUMB: Can I just give some dates and
6 then you tell me if they work.

7 Is September too late, beginning of September? Can
8 we do that?

9 MR. SLATER: What day did you say, Your Honor?

10 CHIEF JUDGE BUMB: Well, I'm just asking generally
11 speaking, is the beginning of September okay?

12 MR. SLATER: The first week would be difficult.

13 MR. OSTFELD: Yeah. For me as well.

14 CHIEF JUDGE BUMB: Well, I'm just asking in terms of
15 preparing for trial.

16 MS. ALLON: No. I think it would be ideal.

17 CHIEF JUDGE BUMB: What?

18 MS. ALLON: September instead of August, from our
19 witnesses' perspective.

20 CHIEF JUDGE BUMB: Oh, okay.

21 MR. STANOCH: Judge, I hate to do this. I was just
22 going to say if there are some late August dates, that might be
23 helpful, given professional and academic obligations of all
24 three of the experts that have to come in here.

25 MR. SLATER: You mean the --

1 CHIEF JUDGE BUMB: I can't do the last week of
2 August.

3 MR. STANOCH: Okay. Okay. Sorry, Adam.

4 CHIEF JUDGE BUMB: So I'm going to give you some
5 dates, and then you work with your experts to tell me, and I'll
6 reserve the dates for now.

7 Again, I have a few criminal matters, so I may have
8 to just...

9 Okay. 9/10 in the afternoon.

10 9/9, all day.

11 And 9/17, most of the day.

12 And 9/18, most of the day.

13 So my least preferred date is the 9th. But the
14 others -- I mean, if it has to be, it has to be. But those are
15 three and a half days that I think you should be able to get
16 the experts in. So I need to hear from Afnan, Stiroh, Gibson,
17 and Conti.

18 And is the issue -- there's an issue on Cowhey,
19 right? I have to rule on that?

20 MR. SLATER: It's -- it's more of an issue that
21 probably we could address with Judge Vanaskie, because it
22 relates to the punitive damages discovery.

23 CHIEF JUDGE BUMB: Okay. So we'll refer that to
24 Judge Vanaskie. Thank you.

25 Okay. We have a couple more minutes and then I will

1 adjourn for the day.

2 You folks have been very good.

3 MS. ROSE: Your Honor, I'm so sorry to interrupt.

4 CHIEF JUDGE BUMB: Yeah.

5 MS. ROSE: I just wanted to, on the issue of the
6 *Daubert*, our -- the Afnan motions are cross-motion by the
7 plaintiffs to exclude more of Afnan. But our motion is that if
8 the, as Your Honor said, some of the paragraphs of Afnan are
9 excluded, the same paragraphs should be excluded for Plunkett
10 and Najafi. So -- and then there was some discussion about if
11 they had different qualifications or if they had different
12 reasons to say these things. So I think if Dr. Afnan is
13 coming, Dr. Najafi and Dr. Plunkett should also be there, as we
14 are -- the point of our motion is that if Afnan can't discuss
15 adulteration, then Najafi and Plunkett's opinions on that
16 should be excluded.

17 CHIEF JUDGE BUMB: But they had different
18 qualifications. I thought that was the answer.

19 MS. ROSE: So the defendants dispute that. The
20 defendants take the position Najafi and Afnan are very
21 well-suited. They both have Ph.D.s in chemistry. They both
22 are FDA experts. Afnan worked at the FDA. So I'm not taking
23 plaintiffs at face value that they have very different
24 qualifications. I think they line up very similarly.

25 CHIEF JUDGE BUMB: So do this in preparation for

1 Afnan, for the hearing for him, is that you will give to me the
2 paragraphs that you believe were permitted but not permitted
3 for Afnan that you believe should have been along with their
4 qualifications and I'm going to pose the question to him.

5 MS. ROSE: Okay. Sorry. Just so I'm clear, submit
6 to you the paragraphs for Najafi and Plunkett that I believe
7 should have been excluded?

8 CHIEF JUDGE BUMB: Yes. Or you believe should permit
9 Afnan to say the same thing. Isn't that what you're saying to
10 me?

11 MS. ROSE: Yeah. What I'm saying is that it's to the
12 extent --

13 CHIEF JUDGE BUMB: This is the goose/gander?

14 MS. ROSE: This is the goose/gander.

15 CHIEF JUDGE BUMB: Yeah.

16 MS. ROSE: So to the extent the Court decides that
17 Afnan -- some of Afnan's opinions are out, then it's our
18 position that Dr. Najafi and Dr. Plunkett's opinions on those
19 same issues should be out. Plaintiffs have raised --

20 CHIEF JUDGE BUMB: And that's what I want you to do.
21 What are those sections that you say should be out. I want to
22 have those ahead of the *Daubert* hearing.

23 MS. ROSE: Okay.

24 CHIEF JUDGE BUMB: And the qualifications of
25 Plunkett, and who else? Those --

1 MS. ROSE: Najafi. Dr. Najafi.

2 CHIEF JUDGE BUMB: Najafi, okay. And then I want you
3 to show me which portions were rendered stricken by Afnan.
4 Because you say they shouldn't have been rendered stricken
5 because that's the goose/gander argument.

6 MS. ROSE: Sure. And --

7 CHIEF JUDGE BUMB: Okay. Because after I hold the
8 *Daubert* hearing, I may permit the introduction of those
9 paragraphs and it moots out your argument.

10 MS. ROSE: Okay.

11 CHIEF JUDGE BUMB: Does that make sense?

12 MS. ROSE: It does make sense.

13 And my one remaining question is, should we use --
14 you gave rulings this morning that were different from Judge
15 Kugler's rulings. There were three paragraphs.

16 CHIEF JUDGE BUMB: You're going to use the rulings
17 that I gave today.

18 MS. ROSE: Okay. Perfect. Thank you so much, Your
19 Honor.

20 CHIEF JUDGE BUMB: Yeah. And it may moot it out.
21 I'm getting probably just a little too tired. But I think that
22 that's the better way to go, because it may moot out your
23 argument if I permit those paragraphs back in, so to speak,
24 okay?

25 MS. ROSE: I appreciate it, Your Honor.

1 CHIEF JUDGE BUMB: Okay.

2 MS. ALLON: Your Honor.

3 CHIEF JUDGE BUMB: Yeah.

4 MS. ALLON: Our motion in limine -- sorry, Jessica.
5 Go ahead. No problem.

6 MS. DAVIDSON: I just had a question about the
7 *Daubert* hearing.

8 Your Honor, we haven't been before you at a *Daubert*
9 hearing before, and I just want to know, do you want us to meet
10 and confer with plaintiffs about how it would set up or do you
11 have a preference as to how the questioning goes?

12 CHIEF JUDGE BUMB: The proponent of the -- the
13 proponent of the witness starts and sets up the background, the
14 qualifications under 702 and what the opinion is and the
15 reliability. Goes through all of the factors under 702, okay?
16 And then subject to cross. I'm primarily looking for whether
17 or not 702 is satisfied. Okay.

18 MS. DAVIDSON: Thank you.

19 CHIEF JUDGE BUMB: But in this context that's just
20 been raised, I'm also now going to pay attention to whether or
21 not those paragraphs should or should not have come in --
22 should have come in.

23 MS. DAVIDSON: Okay. Thank you.

24 MS. ALLON: So on number 16, which was the motion in
25 limine Your Honor said would be helpful to have further

1 briefing about the replacement products.

2 CHIEF JUDGE BUMB: Yes. I'm intrigued by this
3 argument.

4 MS. ALLON: Yes. So I was going to suggest --

5 CHIEF JUDGE BUMB: Because -- go ahead.

6 MS. ALLON: Oh, I'm sorry. I was going to say,
7 should we do that briefing so it's completed before the *Daubert*
8 hearing in case Your Honor wants additional argument on it? Or
9 we could do it the same time as you hear from Dr. Stiroh.

10 CHIEF JUDGE BUMB: Yes, I do.

11 MS. ALLON: Okay. So we'll just work with the
12 plaintiffs.

13 CHIEF JUDGE BUMB: Yes. You work with the plaintiffs
14 or with Judge Vanaskie and come up with a schedule to get it to
15 me. But, you know, definitely, you know, more than a week
16 ahead of these hearings, so it would be helpful to me.

17 What's intriguing about that argument is this is a
18 warranty claim. And this is --

19 MS. ALLON: It is very -- it is very -- I'll give the
20 plaintiffs this, it's a very interesting issue of how the law
21 that I cited applies in a warranty case.

22 CHIEF JUDGE BUMB: Right.

23 MS. ALLON: And I do think you're right, Your Honor,
24 that it merits further briefing. So I found it interesting.

25 CHIEF JUDGE BUMB: Yeah. It's an intriguing issue.

1 But we'll see. Yeah.

2 Should we do more work or should we just call it a
3 day?

4 You folks look through your trial briefs and see if
5 you can resolve some of these issues that I don't have to
6 resolve. I think that, you know, and then you'll write me a
7 letter and say that you've all conferred and you resolved them
8 all and there's nothing further.

9 So I think what we'll do is -- so what do you owe me?
10 You owe me the questionnaires. I'll take a look at that. I'll
11 give you my rulings on that. Jury charges, did you all start
12 working on jury charges? I know there's a --

13 MR. DAVIS: Your Honor, this is John Davis for the
14 plaintiffs.

15 We submitted a set; defendants submitted a set in
16 preparation for the last -- the March trial.

17 CHIEF JUDGE BUMB: Okay. Are they joined?

18 MR. DAVIS: Since then, Judge Kugler obviously issued
19 several rulings, including the summary judgment opinion. So
20 those will have to be modified to take into account the summary
21 judgment rulings.

22 CHIEF JUDGE BUMB: Okay. And so are they joined?

23 MR. DAVIS: Joined in the sense like plaintiffs and
24 then defendants?

25 CHIEF JUDGE BUMB: Yeah, joint.

1 So this is what I require under my rules: They have
2 to be -- the jury charges have to be joint. They have to be a
3 joint effort. To the extent that there are disputes and you
4 can't agree on the charge, they are in the back or they're
5 supplemental, whatever. But what I don't do is I don't look at
6 both sets.

7 MR. DAVIS: Got it.

8 CHIEF JUDGE BUMB: And make my own set. You make
9 your own set. You work -- you try to agree on all of them and
10 to the extent that you can't, I'll resolve the ones you can't
11 agree on. So I work from one document.

12 MR. DAVIS: So for clarification, agreed ones, then
13 disputed ones.

14 CHIEF JUDGE BUMB: Yeah.

15 MR. DAVIS: Okay.

16 MR. OSTFELD: Your Honor, on that point, there is a
17 very fundamental disagreement between the plaintiffs and the
18 defendants on the jury instructions. The plaintiffs had taken
19 the view that it is possible to formulate a jury instruction
20 that encapsulate the law of all of the at-issue states. The
21 defendants' position is that there needs to be an instruction
22 as to each of the at-issue states for each of the claims.

23 It may be beneficial for us to get the Court's
24 guidance on that issue.

25 CHIEF JUDGE BUMB: At issue for each claim.

1 MR. OSTFELD: Okay. Thank you, Your Honor.

2 CHIEF JUDGE BUMB: So I'll probably be charging all
3 day.

4 But it is what it is. It would be very helpful
5 though, I think, to present the jury with charts, and then
6 think about putting them in the jury charges themselves, which
7 go to the jury room. I think the jury would be very grateful
8 if you did that.

9 MR. DAVIS: So can I understand your ruling? I think
10 in terms of groupings of states which is how we presented it,
11 and of course Judge Kugler's certification opinion and --

12 CHIEF JUDGE BUMB: So if the states have the same
13 exact law, I'm going to say with respect to Ohio, New York, New
14 Jersey, et cetera, you must find, okay. I'm not going to
15 repeat that ten times if it's all the same.

16 MR. DAVIS: Thank you. Yeah.

17 CHIEF JUDGE BUMB: But if they're different, then I'm
18 going to give separate charges. That's what I understood the
19 question to be.

20 MR. OSTFELD: It's a little bit different, Your
21 Honor.

22 Our view is the substantive elements of the claims
23 are sometimes similar between states, but the way those states'
24 jury instructions express those elements can be very different,
25 so...

1 CHIEF JUDGE BUMB: Well, if the elements are
2 identical, then I'm only going to give one charge. If under
3 their respective state laws there's a reason I should give a
4 separate charge, you're going to show me. But I'm not going to
5 give separate charges just because their model jury charges are
6 different. I'm just going to -- I'm going to make a judgment
7 call and be satisfied that I have sufficiently charged as to
8 each element.

9 MR. OSTFELD: Your Honor, I certainly understand the
10 Court's views on that. And may I respectfully request the
11 opportunity to submit some briefing on this? There's a Seventh
12 Circuit ruling directly on point that says Esperanto jury
13 instructions constitute reversible error. I think it would be
14 beneficial for us to present those points for the Court to
15 consider as you evaluate the appropriate --

16 CHIEF JUDGE BUMB: I'll take a look at it, sure. I'm
17 not interested in creating reversible error.

18 MR. OSTFELD: Thank you.

19 MR. DAVIS: Your Honor, this has been briefed so many
20 times in this case, certification, decertification.

21 CHIEF JUDGE BUMB: What? The jury charge?

22 MR. DAVIS: They attempted to appeal the cert order
23 to the Third Circuit.

24 CHIEF JUDGE BUMB: No. He's talking about the jury
25 charge.

1 MR. DAVIS: Yeah. Well, those are all permissive,
2 Your Honor. You know, none of these model -- you mentioned
3 model jury charges, they all state that a court can deviate
4 from those.

5 CHIEF JUDGE BUMB: No. And that's my -- that's my
6 intuition. That's why I preliminarily ruled the way I did.
7 But when a lawyer stands up and tells me that there's a case
8 directly contrary, then I'm going to listen. And if it's not
9 directly contrary, then maybe the next time I won't listen.

10 MR. OSTFELD: I understand my credibility hangs on a
11 thread, Your Honor. I will do my best to preserve it.

12 (Laughter.)

13 CHIEF JUDGE BUMB: Yeah. So let's see. I would be
14 surprised to see that that's the case law, but I -- you know,
15 look, I would -- I'd like to know that.

16 It just seems to me that if the elements are all the
17 same, that to say to a court that, no, you must use each
18 state's jurisdictions model jury charges when it's really
19 discretionary, in any event, seems to be unusual, but I'll read
20 the case.

21 MR. OSTFELD: Great. Thank you.

22 CHIEF JUDGE BUMB: Okay.

23 Anything else?

24 MS. SMITH: Excuse me, Judge.

25 CHIEF JUDGE BUMB: Yeah, Loretta.

1 MS. SMITH: Would you consider ruling on Judge
2 Vanaskie's appeal, on the appeal of Judge Vanaskie?

3 CHIEF JUDGE BUMB: Yeah. I'm going to wait until you
4 have an opportunity to respond to what Judge Vanaskie just
5 ruled yesterday, right?

6 MS. SMITH: And the other thing is, do you want a set
7 meeting date for the next conference, the next what's called
8 case management conference?

9 JUDGE VANASKIE: We could do that.

10 CHIEF JUDGE BUMB: You want to set one, Judge?

11 All right. Judge Vanaskie is going to set a next
12 meeting date for the case management.

13 (Court conferring with Judge Vanaskie.)

14 (Discussion was held off the record.)

15 MS. ALLON: I wanted to address the pretrial order,
16 Your Honor.

17 CHIEF JUDGE BUMB: Yes.

18 MS. ALLON: So we submitted to Judge Kugler a
19 pretrial order.

20 CHIEF JUDGE BUMB: Yeah.

21 MS. ALLON: I think that with the benefit of today,
22 we could take another look at it, and it will be something
23 you'll be much happier with than what we submitted already. A
24 number of the disputes have been resolved and we could work
25 through them. So I think we should take that back --

1 CHIEF JUDGE BUMB: Yeah.

2 MS. ALLON: -- and then submit a new one to you
3 whenever you would like.

4 CHIEF JUDGE BUMB: Yeah. I mean, I saw it. It's in
5 here, and I read it.

6 MS. ALLON: Well, don't read it all.

7 CHIEF JUDGE BUMB: What I want you to do is to work
8 on submitting a final pretrial order. Because as you folks
9 know, the final pretrial order is "the case." And then have it
10 ready for Judge Vanaskie to go over with you all and to approve
11 it by the time the case management is set, okay?

12 MS. ALLON: Yes, Your Honor.

13 JUDGE VANASKIE: And would it be all right if we had
14 our case management conference August 14th?

15 MR. SLATER: Yes.

16 MS. ALLON: So we have a mediation that day in
17 another case actually.

18 But also, Adam, is that going to be enough time to do
19 the joint pretrial order? I don't think so.

20 MR. SLATER: It might not be. We might not want to
21 tether the two. If you want to see us earlier, Judge.

22 MS. ALLON: Right.

23 MR. SLATER: I think we have a discovery conference
24 scheduled, but it might be on the 31st. Am I making that up?

25 (Counsel conferring.)

1 MS. ALLON: August 31st?

2 MR. SLATER: July 31st, but that doesn't -- that's a
3 discovery conference.

4 JUDGE VANASKIE: That's a discovery conference.

5 MR. SLATER: For any open issues. So I guess the
6 issues we deferred for Your Honor, we would bring on for that
7 day so far. But I don't think we could get -- there's no way
8 we could get the pretrial order done by then.

9 JUDGE VANASKIE: How about by August 21st?

10 MR. SLATER: That's a month.

11 Could we, in the interest of compassion, for the many
12 people who have to work on this, say August 21st is the target.
13 We will work very hard to get it done. If we jointly say we
14 can't get it done by then, let you know where we are and go
15 from there?

16 JUDGE VANASKIE: Let me know sufficiently in advance
17 that you won't be able to get it done by then.

18 MR. SLATER: Yeah. I'm just trying to take into
19 account summer.

20 JUDGE VANASKIE: That's fine, sure.

21 MR. SLATER: And it's a tremendous amount that's in
22 there, so I'm trying to think about everybody's...

23 MR. OSTFELD: I also rise in support of compassion.
24 And perhaps I'm also wondering if we should wait until after
25 the Rule 702 rulings have issued, after those hearings, because

1 that will affect the content of the final pretrial order.

2 MR. SLATER: You mean to finish it?

3 MR. OSTFELD: To finish it. Yeah.

4 MR. SLATER: Yeah. I'm not worried about that.

5 Because there's a lot we could do anyway. There's exhibits we
6 know are coming out.

7 CHIEF JUDGE BUMB: Yeah. I think you should have the
8 conference with Judge Vanaskie. I'm not saying that the final
9 pretrial order has to be done by then, okay.

10 MR. SLATER: Okay.

11 CHIEF JUDGE BUMB: But it should be -- the final
12 pretrial -- let me give you the deadline for the final pretrial
13 order. That will be helpful, and you folks can work backwards.

14 October 11th.

15 MS. ALLON: And, Your Honor, is there going to be a
16 final pretrial conference?

17 CHIEF JUDGE BUMB: With Judge Vanaskie.

18 MS. ALLON: Oh, okay. It's going to be with Judge
19 Vanaskie, okay.

20 (Counsel conferring.)

21 CHIEF JUDGE BUMB: So that could be -- if
22 October 11th works for you, Judge, we could do it then. You
23 could do it then. You could have the submission and the
24 conference then. And if it's approved, then that's it. If
25 there has to be modifications, then we have a couple weeks to

1 play with.

2 So the only other issue then that -- you folks are
3 going to work on the motions in limine inside the trial briefs.
4 Try to work those through. And then the only other issue that
5 I think that is pending before me, other than the *Dauberts* and
6 the issue with Afnan, is the Special Master Order 98. That's
7 the sanctions order.

8 So when are you folks intending to respond to what
9 Judge Vanaskie ruled yesterday?

10 MS. DAVIDSON: Your Honor, could we have a week?

11 CHIEF JUDGE BUMB: Okay. A week.

12 And do you intend to file anything?

13 MR. SLATER: I think we do. I don't know that we
14 could get it done within one week.

15 CHIEF JUDGE BUMB: What more is there to say?

16 MR. SLATER: Uhhh, if you say get it done in a week,
17 we'll get it done in a week, right?

18 CHIEF JUDGE BUMB: Okay.

19 MR. SLATER: I'm looking at the brains of the
20 operation.

21 CHIEF JUDGE BUMB: August 2nd.

22 MR. SLATER: Thank you, Judge.

23 CHIEF JUDGE BUMB: August 2nd. Okay.

24 Because if I gave you August 5th, then that means you
25 all have to work on the weekend and working hard enough, and

1 I'm not going to do that, okay?

2 (Counsel conferring.)

3 CHIEF JUDGE BUMB: Okay. So then I'll probably just
4 give you a ruling -- well, no.

5 Yeah, I'll give you a ruling probably in written form
6 on that.

7 MS. DAVIDSON: I'm sorry, Your Honor. I'm a little
8 confused. Are you envisioning simultaneous filings?

9 CHIEF JUDGE BUMB: Yes. Yes.

10 MS. DAVIDSON: Thank you.

11 CHIEF JUDGE BUMB: So I gave you to August, whatever
12 I just said.

13 MS. DAVIDSON: Oh, great. You gave me extra time.
14 Thank you.

15 MR. OSTFELD: So sorry. One other point and
16 Mr. Honik was just kind enough to point out. Yom Kippur begins
17 the evening of October 11th. Hopefully we would have the final
18 pretrial order done before sunset. But we sort of tied the
19 hands of those of us who observe.

20 CHIEF JUDGE BUMB: That's Yom Kippur on the 11th,
21 October 11th.

22 (Counsel conferring.)

23 (Discussion was held off the record.)

24 MR. OSTFELD: That's the filing date for the final
25 pretrial order. And last time we were filing kind of well

1 after hours.

2 CHIEF JUDGE BUMB: No. I had --

3 (Counsel conferring.)

4 MR. SLATER: The 11th.

5 CHIEF JUDGE BUMB: I had envisioned that you would be
6 meeting with Judge Vanaskie on the 11th in the morning.

7 MR. OSTFELD: Oh, in the morning. Okay.

8 MS. ALLON: So we'll file on the 10th.

9 MR. OSTFELD: Okay. So we'll file on the 10th.

10 CHIEF JUDGE BUMB: File on the 10th, and then you'll
11 have the pretrial --

12 MS. ALLON: And we'll have the pretrial conference in
13 the morning of the 11th.

14 CHIEF JUDGE BUMB: In the morning of the 11th.

15 MR. OSTFELD: Okay. Can the meeting with Judge
16 Vanaskie be by Zoom?

17 CHIEF JUDGE BUMB: Yes. I presumed it would be.

18 JUDGE VANASKIE: All right.

19 MR. OSTFELD: Thank you.

20 MS. ALLON: Thank you.

21 CHIEF JUDGE BUMB: Anything else?

22 MR. SLATER: Only a fool would say "yes" to that one.

23 (Laughter.)

24 CHIEF JUDGE BUMB: Good to meet you all. Good to see
25 you all.

1 Enjoy your summer. But I'll see you sometime I guess
2 for the *Dauberts*, all right?

3 MR. SLATER: Thank you very much. Thank you.

4 MS. LOCKARD: Thank you, Your Honor.

5 MS. DAVIDSON: Thank you, Your Honor.

6 THE COURTROOM DEPUTY: All rise.

7 (Proceedings concluded at 5:14 p.m.)

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9 **FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE**
 - - - - -

10 I certify that the foregoing is a correct transcript
11 from the record of proceedings in the above-entitled matter.

12
13
14 /S/John J. Kurz, RDR-RMR-CRR-CRC

July 26, 2024

15 Court Reporter/Transcriber
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<p>CHIEF JUDGE BUMB: [1021] JUDGE VANASKIE: [10] 14/20 130/25 284/11 306/9 307/13 308/4 308/9 308/16 308/20 312/18 MR. BERNARDO: [6] 8/16 8/23 9/3 105/21 106/5 106/13 MR. DAVIS: [11] 301/13 301/18 301/23 302/7 302/12 302/15 303/9 303/16 304/19 304/22 305/1 MR. HARKINS: [79] 8/6 37/8 39/10 39/13 39/17 39/20 41/12 41/19 41/22 42/11 42/13 44/11 44/14 44/17 47/23 48/1 48/17 49/11 49/19 49/23 50/8 50/14 51/21 52/14 53/6 53/10 54/4 54/11 55/11 55/13 55/18 55/24 56/12 56/17 62/14 67/17 92/14 92/17 116/1 131/13 133/10 133/15 133/24 134/23 135/1 135/7 137/14 155/20 156/12 156/17 156/19 157/2 157/6 157/22 158/11 158/14 159/5 159/7 159/9 160/1 161/5 161/10 161/24 163/8 163/12 164/3 164/18 164/21 165/6 165/12 166/11 169/2 169/5 169/23 170/8 172/23 173/12 199/18 227/25 MR. HONIK: [14] 6/8 6/22 166/17 167/5 167/9 167/22 168/4 168/7 168/11 168/20 216/14 216/21 217/20 247/21 MR. 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WHITELEY: [1] 6/25 THE COURT REPORTER: [3] 68/9 117/24 291/20 THE COURT: [7] 161/19 162/4 166/13 167/6 172/21 183/12 189/11 THE COURTROOM DEPUTY: [7] 6/4 86/5 86/7 154/8 154/10 238/7 313/6 <hr/>\$ \$10 [2] 233/16 233/17 \$5 [2] 233/24 233/25 \$6 [1] 233/25 <hr/>' '16 [1] 70/12 <hr/>/ /S/John [1] 313/14 <hr/>0 00046 [1] 45/10 02116 [1] 2/24 023 [1] 72/1 024 [1] 72/1 04112 [1] 2/7 0677 [1] 5/10 07068 [1] 1/18 07102 [1] 3/19 07932-0677 [1] 5/10 08043 [1] 3/7 08101 [1] 1/8 08540 [2] 3/22 4/24 <hr/>1 10 [7] 112/9 115/19 139/16 221/17 221/19 222/2 295/9 100 [2] 2/9 3/18 10001 [1] 2/13 1001 [1] 4/13 10022 [1] 4/7 1025 [1] 3/7 103 [1] 1/18 10th [3] 312/8 312/9 312/10 11 [2] 4/17 225/23 1100 [1] 1/14 11:30 [2] 86/3 86/6 11:46 [1] 86/6 11th [9] 291/5 309/14 311/17 311/20 311/21 312/4 312/6 312/13 312/14 12 [1] 255/9 120 [1] 32/10 124 [1] 138/2 128 [1] 2/13 12:39 [1] 131/23 12:43 [1] 131/23 138 [4] 138/8 138/12 138/22 139/21</p>
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